I. INTRODUCTION

1.1 Background

In Indonesia, with a large population, the demand for biomedical devices becomes crucial to meet the continuously increasing healthcare needs. Currently, the use of Implantable Medical Devices (IMDs) in Indonesia is not detailedly regulated. It is important to note that regulating standards and specifications for IMDs has a significantly impactful effect, particularly concerning the health and well-being of the human body. By establishing appropriate regulations and specifications, it can ensure that all IMDs function efficiently and safely. With clear regulations and accurate specifications in place, the use of IMDs can support more precise and secure health monitoring for individuals.

Implantable wireless devices (IMDs) have the capability to acquire physiological data, such as glucose levels, temperature, and heartbeat, from diverse regions of the patient's body. Subsequently, this data is transmitted wirelessly to an external monitoring device [1]. The inherent implantable nature of IMDs introduces size constraints, necessitating the development of miniaturized versions that do not compromise their functionality [2].

The design of a compact implantable antenna, a crucial element of any IMD, poses a formidable challenge. Coordinating the review of this manuscript and approving it for publication was Chan Hwang See. Implantable antennas exhibit distinct radiation characteristics compared to antennas in free space, requiring them to undergo miniaturization while adhering to a spectrum of patient safety criteria [3] and meeting various specified conditions [4].

In the "*Peraturan Menteri Komunikasi dan Informatika Peraturan Direktur Jenderal Sumber Daya dan Perangkat Pos dan Informatika (SDPPI) Nomor 161 tahun 2019 tentang Persyaratan Teknis Alat dan/atau Perangkat Telekomunikasi Short Range Device*" The regulations currently only focus on standardization for devices used in proximity and/or on the body. However, these regulations do not specifically address the specifications and standards for devices inserted into the body, known as Implantable Medical Devices (IMDs)[5].

The aim of the proposed research is to design and simulate one of the implementations of IMDs applications, namely the Implantable Antenna as a proof. The main outcome of this research will be the specification values of Specific Absorption Ratio, EIRP, and several other parameters, intending to provide standard and drafting for Radio Characteristics and Technical Specifications of Implantable Medical Devices (IMDs) applications in Indonesia.

1.2 Problem Identification

In the context of the increasingly widespread and popular use of biomedical devices in Indonesia, particularly implantable medical devices, it is imperative to ensure that user safety is a top priority. This is especially critical concerning the radiation exposure to the human body, known as Specific Absorption Ratio (SAR), the power used, and compliance with specified frequencies. Implantable devices differ significantly from other devices as they are located within the human body. Therefore, it is crucial to ensure they are meticulously designed to safeguard user health and comfort.

Implantable medical devices must operate at specific frequencies that are safe for the human body. Additionally, the power output of these devices must be closely monitored, adhering to regulations to strike a balance between device performance and its impact on the human body. The value of the Specific Absorption Ratio (SAR) is another vital indicator that requires attention. SAR measures the extent to which the human body absorbs electromagnetic energy from the device. The SAR value must always remain within the safe limits set by health authorities.

However, a significant challenge is the absence of specific specifications regarding implantable medical devices in Indonesia. Therefore, clear and stringent regulations are needed to ensure that implantable medical devices used in Indonesia are safe and comply with established health standards.

1.3 Objectives

This research will generate the design of an implantable antenna as a proof for the key specifications of implantable medical devices that are most suitable for the safety and health of the human body, tailored to the needs of users in Indonesia.

This will be achieved by examining the existing regulatory conditions in Indonesia, conducting a literature review, benchmarking against regulations in other countries, and designing the implantable antenna.

Subsequently, analyzing the results related to the antenna design and identifying specifications related to international and Indonesian regulations and requirements will assist stakeholders, such as manufacturers, regulators, and consumers, in understanding and complying with applicable legal provisions. Therefore, it is expected that the proposed specifications for implantable medical devices for use in Indonesia will enable manufacturers to develop products that effectively meet local needs. These specifications will encompass radiation levels, permissible power levels, and the frequencies used.

1.4 Hypothesis

This research will result in the design of an implantable antenna as a proof and the formulation of technical specifications that comply with regulations. The Specific Absorption Ratio (SAR) values and power levels will conform to standards and be safe for the human body. The frequency spectrum of use will be regulated according to frequency harmonization. With clear regulations, safe specifications, and a better understanding of implantable devices, it is expected that the use of this technology can support more accurate and secure health monitoring for individuals in Indonesia.

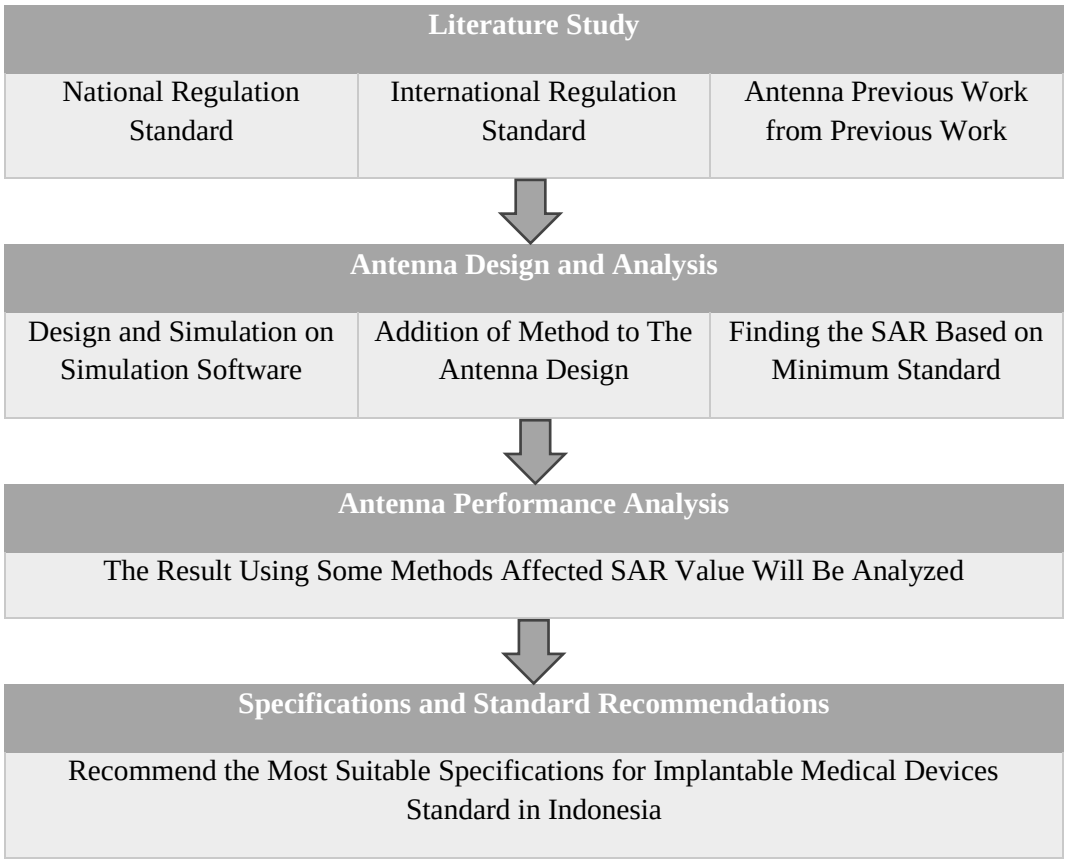
1.5 Scope of Work

Scope of research in this study as follows :

1. This research will focus on the design of an Implantable Antenna as proof of an implementation of Implantable Medical Devices (IMDs).
2. The scope of this study is solely on the design of the Implantable Antenna as a proof, without engaging in physical fabrication.
3. The research is centered around the standard specifications derived from the design outcomes, which can be utilized as usage standards in Indonesia.

4. The body phantom to be used as a medium in this study will exclusively involve a skin phantom and deep tissue

1.6 Methodology



This research begins with a literature review of existing regulations in Indonesia, international regulations, and a state-of-the-art analysis of several previous studies. Following this, the antenna will be designed using 3D design software. Subsequently, various methods will be incorporated into the antenna with the potential to reduce Specific Absorption Rate (SAR) values. The focus will then shift to optimization to identify SAR values that align with established standards. Upon achieving specifications in accordance with standards, recommendations for the specifications and standardization of implantable medical device usage in Indonesia will be provided as the output of this research.

1.7 Research Method

The writing structure outlined in this research consists of five chapters with the following arrangement and explanations:

CHAPTER I : INTRODUCTION

This chapter provides an explanation of the background, research objectives, problem formulation, scope of the study, research methodology, and the research writing structure.

CHAPTER II : BASIC CONCEPTS

This chapter discusses the fundamental concepts of the research and the theories that underlie the formation of the study.

CHAPTER III : MODEL AND DESIGN SYSTEM

This chapter presents the process of designing and planning the technical study related to the use of Implantable Antenna specifications and recommendations for relevant regulations.

CHAPTER IV : RESULTS AND ANALYSIS

This chapter contains the results and analysis of the proposed technical specifications and regulatory recommendations.

CHAPTER V : CONCLUSION AND RECOMMENDATIONS

In this chapter, conclusions drawn from the entire design process are discussed, along with recommendations that can aid in the development of future research.