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PRINCIPLES OF SAFETY AND PERFORMANCE FOR MEDICAL HYPERBARIC CHAMBERS: GUIDELINES FOR REGULATORY SUBMISSION

Prepared by:

ASME PVHO Subcommittee
on Medical Hyperbaric Systems

ASME STANDARDS
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FOREWORD

In the United States, Hyperbaric Oxygen Therapy (HBOT) is considered to be a medical treatment and requires a physician's prescription. Furthermore, Hyperbaric Chambers intended to be used to administer HBOT treatments require Federal Drug and Food Administration's (FDA) approval. Similar regulatory submissions such as the Global Harmonization Task Force (GHTF) document "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" are required in other countries.

This publication provides guidance for completing such regulatory submissions as well as principles of safety and performance of Pressure Vessels for Human Occupancy intended for use as medical devices. The FDA's regulatory submission package encourages compliance to the ASME PVHO-l Standard, and therefore compliance with the PVHO-l Standard requirements pertaining to the manufacture of Hyperbaric Chambers are recommended in this Guide.

The work contained in this publication was started in 2007 by the PVHO Subcommittee on Medical Hyperbaric Systems. The technical review was conducted by the ASME Pressure Vessel for Human Occupancy (PVHO) Committee over a period of three years. The PVHO Committee which conducted the technical review consists of twenty three members and two delegates representing several industry sectors which include manufacturers, users, insurance companies, regulatory and governmental agencies, as well as five countries: the USA, Canada, England, Germany and Australia.

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ABSTRACT

This document is intended to provide guidance with development, review and approval of regulatory submissions involving hyperbaric chambers. While there are specific standards and regulatory requirements for the design, production and regulatory approval of medical devices and pressure equipment, there has not been regulatory guidance for the evaluation of pressure vessels intended for use as medical devices. This document provides assistance for completing regulatory submissions such as the Global Harmonization Task Force (GHTF) document "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" and the United States Food and Drug Administration's (FDA) Premarket Notification process (510k).