

C63 - Electromagnetic Compatibility Committee and Medical Electrical Equipment

DANIEL D. HOOLIHAN
TÜV Product Service, Inc., New Brighton, MN

An ad hoc test method can be used to guide health-care facilities in instituting policies to assure the separation of communication transmitters from susceptible medical devices.

INTRODUCTION

C63 is a United States committee devoted to developing standards in the technical area of electromagnetic compatibility (EMC). The committee is accredited by the American National Standards Institute (ANSI) as a standards developing organization. This means C63 meets strict criteria for a balanced membership to ensure that all interested parties have an opportunity to share in the development of appropriate and timely EMC standards. The goal of C63 is to develop standards when there is a requirement having wide application across many industries or when there is not an obvious candidate organization to develop the needed documents.

The C63 committee was first organized in the 1930s to develop a specification for a radio-interference meter. Throughout its lifetime, C63 has maintained a strong and cooperative relationship with the United States Federal Communications Commission (FCC). Some C63 standards have been incorporated into FCC legal requirements by reference. The most well-known example of this is standard C63.4 - "American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz." The C63.4 standard is used by manufacturers and testing laboratories to check compliance of electronic products (before

marketing) with FCC rules and regulations. Other C63 standards are also available (Table 1).

Also, many technical developments resulting from the development of C63 standards-writing activities have been carried to the international standards organizations for inclusion into appropriate worldwide EMC standards.

The present chairman of C63 is Professor Ralph Showers, an Emeritus Professor of Electrical Engineering at the Moore School of the University of Pennsylvania. The present vice-chairman is Ed Bronaugh, a well-known EMC consultant and past president of the IEEE EMC Society.

C63.2 - 1987	Electromagnetic Noise and Field Strength, 10 kHz to 40 GHz Specifications
C63.5 - 1988	Calibration of Antennas Used for Radiated Emission Measurements in Electromagnetic Interference (EMI) Control
C63.6 - 1988	Guide for the Computation of Errors in Open-Area Test Site Measurements
C63.7 - 1992	Guide for the Construction of Open Area Test Sites for Performing Radiated Emission Measurements
C63.12 - 1987	Recommended Practice for Electromagnetic Compatibility Limits
C63.13 - 1991	Guide on the Application and Evaluation of EMI Power Line Filters for Commercial Use
C63.14 - 1992	Dictionary for Technologies of Electromagnetic Compatibility (EMC), Electromagnetic Pulse (EMP), and Electrostatic Discharge (ESD) (Dictionary of EMC/EMP/ESD Terms and Definitions)
C63.16 - 1993	Guide for Electrostatic Discharge Test Methodologies and Criteria for Electronic Equipment

Table 1. Current C63 Standards.

SUBCOMMITTEES OF C63

At this time, C63 has eight subcommittees which are actively working in different sectors of electromagnetic compatibility. A listing of the subcommittees, their technical areas of responsibility, and their present chairmen follows:

SC-1	Techniques and Developments	Don Heirman
SC-2	Terms and Definitions	Norm Violette
SC-3	International Standardization	Richard Engelman
SC-4	High Voltage Apparatus and Power Lines	Open
SC-5	Public Law 97-259	Don Heirman
SC-6	Conformity Assessment	Dan Hoolihan
SC-7	Unlicensed Personal Communication Service	Art Light
SC-8	Medical Device Test Methods	Dan Hoolihan

In general, each subcommittee has working groups comprised of small groups of people actively working on a given project which may lead to a modification of an existing standard or the development of a new standard.

SUBCOMMITTEE 8 - MEDICAL DEVICE TEST METHODS

Subcommittee 8 was formed in 1995 out of a working group that had originated in Subcommittee 1.

The activity level and interest in medical devices prompted the formation of a separate subcommittee to address the technical measurements of electrical medical devices and their EMC characteristics.

There are three active working groups in Subcommittee 8 of C63:

- Working Group on a Guide for On-Site Testing, Herb Mertel, Chairman
- Working Group on Immunity of Patient-Connected Devices, Howard Bassen, Chairman
- Working Group on Interference between Wireless Phones and Hearing Aids, Steve Berger and Tom Victorian, Co-Chairmen

The Working Group on a Guide for On-Site Testing has an unapproved document (C63.18) which was circulated for ballot the first half of 1996. It was revised to include the comments that were received and has been recirculated to the C63 committee with comments due the first quarter of 1997. The other two working groups have just gotten their Project Initiation Notification System (PINS) paperwork initially approved and are starting to develop their documents.

(PINS is part of the ANSI procedures requiring notification of ANSI by accredited standards developers of the initiation and scope of new activities expected to result in candidate American National Standards. PINS is also used for the initiation of new activities related to revision, reaffirmation, or withdrawal of current American National Standards. This information is a key element in planning and coordinating American National Standards. Directly and materially affected interests wishing to receive more information should contact the standards developer directly within 60 days of the date of publication in the biweekly *ANSI Standards Action*.)

WORKING GROUP ON A GUIDE FOR ON-SITE TESTING

There are many electronic medical devices in use today that have not been designed or manufactured to a recognized national or international standard on EMC. As IEC 601-1-2 (International Standard on Requirements and Tests for EMC for Medical Electrical Equipment) becomes accepted as a mandatory requirement for newly designed medical electrical equipment, the EMC characteristics of equipment in the field will improve. However, the inventory of existing equipment will not necessarily be upgraded to the level of the latest version of IEC 601-1-2.

The question then arises: Is there some way to run a quick and simple EMC test in the field on the existing inventory of equipment to determine its vulnerability to the electromagnetic environment and especially to the abnormal electromagnetic environmental conditions that occasionally occur? This question is being addressed by the Working Group on a Guide for On-Site Testing with its C63.18 (draft) document. This document is entitled "Recommended Prac-

tice for an On-Site, Ad-Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio Frequency Transmitters."

The draft C63.18 document states:

"This document is intended to serve as a guide for health-care facilities in performing radiated electromagnetic immunity testing

The question arises: Is there some way to run a quick and simple EMC test in the field on the existing inventory of equipment to determine its vulnerability to the electromagnetic environment and especially the abnormal electromagnetic environmental conditions that occasionally occur?"

of their existing inventories of medical devices using their existing inventories of radio frequency (RF) transmitters. It applies to medical devices used in typical health-care locations and portable transmitters rated 8 watts or less. It does not apply to transport environments such as ambulances and helicopters, nor to transmitters rated at more than 8 watts."

The objectives of the document are:

- To provide an inexpensive, relatively reproducible test method for estimating the radiated electromagnetic immunity of in-house medical devices that can be performed by hospital engineers using in-house communications equipment (RF transmitters)
- To improve reproducibility and intercomparability of test results between facilities; and
- To use test results when developing policies to manage the use of specific RF transmitters within the facility.

The test method proposed is not intended to be a substitute for rigorous laboratory EMC testing in which the test conditions are more fully controlled.

The test results generated for a particular medical device apply only to that unit and to the frequency, modulation, and field strength characteristics of the RF transmitter used as a source of RF energy.

C63.18 (draft) also provides guidance to health-care facilities in prioritizing their inventory of medical devices to be tested for EMC. Important factors include:

- The criticality of the medical device (whether it is life-supporting, patient-monitoring, diagnostic-oriented, delivers drugs, etc.)
- The potential impact of medical device failure or malfunction on the patient (Is there potential for patient injury or death?)
- Known EMI problems with similar devices
- Whether the medical device contains sensitive components or circuitry (microprocessors, high-gain amplifiers, patient leads)
- Whether RF transmitters are frequently used in the vicinity of the medical device, such as in ambulances and emergency rooms
- Whether the medical device has been noted to perform erratically
- Whether the medical device is repeatedly referred for service, yet when the medical device is tested in the service location, no problem is found

The Recommended Practice document gives some advice on selecting RF transmitters and then devotes several paragraphs to explaining the theory of RF transmitters, including frequency, wavelength, and E and H fields. It also examines effective radiated power and the fact that field strength levels from transmitters diminish with the distance from the source of the RF energy. The actual test method goes into determin-

transmitters in the vicinity of the sensitive equipment.

SUMMARY

C63 is an ANSI-accredited standards developing committee in the technical area of EMC. The full C63 committee has eight subcommittees which coordinate and direct the efforts of a number of working groups comprised of

Health facility personnel should be able to determine which of their electronic medical products would be most susceptible to radiated electromagnetic fields.

ing the characteristics and configuration of the RF transmitters.

The power rating of the transmitter is normally determined by reading the nameplate on the transmitter. This power rating of the RF transmitter is used to determine the initial starting distance of the test. That is, the initial test distance is set up to produce a field strength of approximately 3 volts per meter on the equipment under test. For example, a transmitter having power of less than 600 milliwatts would have an initial test distance of 1 meter from the medical device being tested.

The transmitter is held in the hand in the vertical position. The transmitter is then keyed while observing the effect on the medical device. If a reproducible malfunction is found, the transmitter is moved away from the medical device until the malfunction ceases and the distance is noted. This distance is the approximate minimum separation distance for the medical device and the particular transmitter used.

Using this process, health facility personnel should be able to determine which of their electronic medical products is most susceptible to radiated electromagnetic fields. This knowledge would allow them to devise administrative procedures to allow the successful use of these electromagnetically sensitive products, including controlling the use of cellular phones and other radio

technical experts. One of the subcommittees (SC-8) is entitled Test Methods for Medical Devices and it has a working group developing an ad hoc test method for estimating the immunity of medical devices to radiated signals from licensed transmitters. This ad hoc test method can be used to guide health-care facilities in instituting policies to assure separation of communication transmitters from susceptible medical devices.

DAN HOOLIHAN is presently the Vice-president of the Minnesota Operations of TUV Product Service, Inc. He is the cofounder and past Chief Operating Officer of AMADOR Corporation. Prior to that, he was a manager/engineer with Control Data Corporation. Dan is presently the Vice-President and a member of the Board of Directors of the EMC Society of the IEEE. His positions on the ANSI Accredited Standard Committee on EMC (C63 Committee) include Chairman of Subcommittee 6 on Laboratory Accreditation and Conformity Assessment and Chairman of Subcommittee 8 on Medical Device Test Methods.

Dan is a member of the Association for the Advancement of Medical Instrumentation (AAMI), and The Institute of Environmental Scientists. He is also President of the dB Society. Dan holds an MBA from the University of Minnesota, an M.S. in physics from Louisiana State University, and a B.A. in physics from St. John's University. (612)638-0250.