Electromagnetic Compatibility Aspects of Medical Device Quality Systems

GUIDE TO INSPECTIONS OF ELECTROMAGNETIC

COMPATIBILITY ASPECTS OF MEDICAL DEVICE

QUALITY SYSTEMS

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INTRODUCTION

This guide was prepared by the FDA, Office of Regulatory Affairs, and the Center for Devices and Radiological Health (CDRH), Office of Compliance.

This guide provides FDA investigators with information regarding electromagnetic compatibility (EMC) and how it is likely to be addressed in a medical device firm's Quality

System/Good Manufacturing Practices (QS/GMP) (21 CFR Part 820). Terms throughout this document that are in bold typeface are defined in Appendix A.

THIS DOCUMENT APPLIES ONLY TO ELECTRICALLY POWERED (MAINS OR BATTERY) DEVICES. It includes information on the following:

1. electromagnetic disturbances (EMD), including radiated and conducted emissions, as well as electrostatic discharge (ESD);
2. electromagnetic interference (EMI), susceptibility and immunity;
3. international and voluntary EMCstandards, such as IEC 60601-1-2; (these are not FDA performance standards or mandatory requirements.)
4. areas of the new Quality System regulations where EMC is likely to be addressed;
5. how the regulations apply to EMCissues in continuing production of existing devices, design and production of new or modified devices, and upgrades and recalls of marketed devices; and
6. expectations and limitations of the GMP inspection process regarding EMC.

The Center for Devices and Radiological Health (CDRH) is encouraging firms, many of whom have never considered some of these issues, to begin the process of addressing EMC. The goal is to improve the industry norm, not to penalize industry efforts to design EMC into their devices. There are a number of confounding factors in achieving EMC. Manufacturers can design EMCinto their electrical devices for most expected use environments, depending on design options for proper functioning or electrical safety, intensity or variableness of environments, the

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