Successful Practices for Battery Powered Medical Devices

AdvaMed
Advanced Medical Technology Association

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Successful Practices for Battery Powered Medical Devices

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1.0 INTRODUCTION

Batteries play an increasingly significant role in the overall safety, performance, and reliability of many medical devices. With more medical devices becoming computerized, compact, and mobile, the number of battery powered medical devices will continue to increase.

Though there are numerous advantages to using batteries in medical device applications such as backup power or portability, there are also numerous challenges that can impact design, testing, manufacturing, integration, selection, purchase, storage, maintenance, and use of batteries throughout the total product life cycle.

This document is intended to provide an overview of successful practices for the development, manufacture, and use of batteries in medical device applications. Key factors presented here are applicable for all battery powered medical device types and regulatory classifications. This information is intended for those who develop, manufacture, and maintain battery powered medical devices, especially those who may be new to the field.

Finally, this document is not meant to be a comprehensive guide to the technical details for any particular device application. Instead, it is incumbent on the device manufacturer to seek out expert technical advice when appropriate.

2.0 DEFINITIONS

Anode (negative electrode): The electrode that sources electrons to the external circuit and is oxidized in the electrochemical reaction.

Battery: A device consisting of one or more cells that converts chemical energy contained in its active materials into electrical energy by means of an electrochemical reaction.

Capacity: The quantity of electric charge that a cell or battery can deliver under specified discharge conditions. Capacities are typically provided in units of Ampere hours (Ah).

Capacity fade: That which pertains to the loss of useable capacity of a rechargeable battery. Capacity fade may be both time and cycle dependent.

Cathode (positive electrode): The electrode that accepts electrons from the external circuit and is reduced in the electrochemical reaction.

Cell: The basic electrochemical unit consisting of electrodes, electrolyte, container, terminals and usually separators that is a source of electric energy by means of electrochemical reactions.

Cycle (Cycling): A set of operations that is carried out and is repeated, usually in the same sequence. In a rechargeable battery, cycling may consist of a charge followed by a discharge, or a discharge followed by a charge under specified conditions.

Electrolyte: That which provides the medium for the transfer of charged ions within a cell between anode and cathode.

Float charge: The continuous charging at a low rate using a constant voltage to maintain the battery in a fully charged condition by compensating for losses from self-discharge or intermittent discharges. See also trickle charge.

Gas Gauge Electronics: An internal measurement system incorporated in the battery design to measure state of charge, monitor individual cell voltages, track cycle count, and other functions (a.k.a. Fuel Gauge Electronics).

Gas Gauge User Interface: A visual indicator of the state of charge or remaining battery capacity (a.k.a. Fuel Gauge User Interface).

Hermetic: Complete airtight seal typically defined in terms of the leak rate of helium under specified conditions.

Impedance: A generic term that reflects not only resistance, but also all other phenomena that may cause voltage drop in response to a constant or transient current (e.g., capacitance, inductance, electrochemical kinetics, etc.).

Leak-free: When no visible dried electrolyte is on the exterior of the cell or battery.

Primary cell: A cell that is not designed to be electrically recharged [IEC 60050-482].

Secondary cell: A cell that is designed to be electrically recharged [IEC 60050-482].

Self-discharge: The loss of charge via direct anode/cathode reaction inside the cell (due to limited solubility, for example) or by parasitic reactions between either the electrode material or the electrolyte. Self-discharge may be partially irreversible and partially reversible for rechargeable batteries. The reversible loss of charge can be recovered when the cell is recharged.

Separator: A component of a cell, made up of material permeable for ions, which prevents electric contact between cell plates of opposite polarity within a cell [IEC 60050-482].

Service life: The full life of the battery from time of manufacture through end of service.

Shelf life, cell or battery: The time from manufacture of a cell or battery to installation in a battery powered medical device.

Shelf life of an installed battery in a battery powered medical device: The time from installation of the cell or battery in a device to the time the device is put into operation or the battery is recharged.

Smart Battery: A battery with integrated electronics to provide state of charge information, control the charge process, and electronic protection to ensure safe operation (a.k.a. Smart Battery System).

Thermal Runaway: An unstable condition in which a rapid rate of heat generation exceeds the rate of heat dissipation which can lead to the destruction of the battery.

Trickle charge: Continuous charging at a low rate using a constant current to maintain the battery in a fully charged condition by compensating for losses from self-discharge or intermittent discharges. See also float charge.

Usage Window: The range of voltage, current, capacity or energy, and environmental conditions within which the battery should be used to deliver the expected performance.

Use environment: The environment in which the battery powered medical device is handled, operated, and stored.

3.0 BASIC BATTERY SPECIFICATIONS

In This Section:

- General description of cell chemistry and types
- General description of battery systems
- Nominal performance characteristics

The basic battery specifications provide a general description of the cell or battery. Information such as the cell chemistry, cell or battery construction, nominal voltage, nominal capacity or energy and shelf life give the user an overview of cell or battery design and performance expectations.

3.1 Cell Chemistry

Cell chemistry, given as the anode and cathode active material types, should be identified in the specification and data sheet. In some cases, the electrolyte or more detailed chemical descriptions of the anode and cathode active materials may be appropriate to operational conditions and performance characteristics, such as extreme environmental conditions.

If purchased from an outside source, some of the information about cell chemistry can be found in Section 3 of the MSDS (material safety data sheet) for the battery, sometimes called a product safety data sheet (PSDS) or safety data sheet (SDS). This may be obtained from the manufacturer or distributor. Some suppliers may also provide this information in a cell or battery data sheet.

Examples of selected, commonly used cell chemistry types:

- Lead acid ($Pb/PbSO_4$)
- Lithium-manganese dioxide (Li/MnO_2)
- Alkaline zinc-manganese dioxide (Zn/MnO_2)
- Nickel-metal hydride (NiMH)
- Nickel-cadmium (NiCd)
- Lithium ion (graphite/$LiCoO_2$, graphite/$LiFePO_4$)

For standardized cell chemistries and sizes, an IEC designation may be available for defining cell chemistry and the dimensions of the cell. See IEC 60086-1, IEC 60086-2 and IEC 60086-3, IEC 60095, IEC 61960 for standard cell types.

Examples of standard cell types:

- LR06 (alkaline zinc-manganese dioxide AA cell)
- BR1225 (Lithium-carbon monofluoride coin cell)
- ICR18650 (Lithium ion – lithium cobalt oxide – cylindrical cell)

3.2 Cell Type

A description of the cell's functional type—needs to be identified with this information:

- Primary (nonrechargeable) or secondary (rechargeable)

- Form factor (cylindrical, prismatic, pouch)
- Electrode (anode or cathode) that limits total discharge capacity of the cell or battery.

Also, include general information on cell construction that may be critical for the target application or if there are multiple types of cell construction available, such as:

- Hermetically sealed
- Maintenance-free sealed lead acid (SLA)
- Absorbent glass matt (AGM)
- Valve-regulated lead acid (VRLA)

3.3 Cell Voltage (Also see Section 5.0)

The nominal voltage of the cell should be given in the specification and data sheet. This can be the approximate open circuit voltage prior to use, particularly for primary cells. Open circuit voltage is the voltage without an external load attached. Open circuit voltage measurements should be made using a high input impedance (1 MΩ minimum) voltage meter. Alternatively, the nominal cell voltage for a secondary cell may be quoted as the average open circuit voltage between the maximum and minimum voltage of the discharge range. Voltage measurement conditions (particularly temperature) should be specified. The nominal cell voltages for standard cells may be found in the relevant standards (for example, IEC 60086-1 for nonaqueous primary cells). Cell and battery suppliers may provide a cell or battery data sheet with this information.

The operating voltage range consisting of the maximum charge voltage and minimum discharge voltage cutoffs should be defined.

3.4 Cell Capacity or Energy (Also see Section 5.0)

The nominal cell capacity or energy, along with the pertinent test environmental conditions (particularly temperature), should be listed in the specification and data sheet. Capacity is typically given in ampere-hours (Ah) or milliampere-hours (mAh = 0.001 x Ah). Energy is typically given in watt-hours (Wh) or milliwatt-hours (mWh = 0.001 x Wh). Capacity and energy of a cell are specific to a particular set of discharge parameters and environmental conditions, which should be provided. Capacities for more than one set of conditions may be appropriate if cells are to be used for different applications. This information should be captured under “Discharge Characteristics.”

3.5 Pack Configuration (Also see Section 6.0)

For battery packs, the arrangement of cells in a completed pack designed for the target application should be furnished.

Example: Three groups of two cells, connected in parallel that are then connected in series (3s2p).

3.6 Pack Voltage (Also see Section 5.0)

The nominal voltage of the assembled battery pack should be given. See 3.3 Cell Voltage for nominal voltage definitions. Cell and battery suppliers may provide a battery data sheet that gives this information.

3.7 Pack Capacity or Energy (Also see Section 5.0)

The nominal battery pack capacity or energy, along with the pertinent environmental conditions for the testing (particularly temperature), should be listed in the specification or data sheet. The values for capacity and energy of a battery pack are specific to a particular set of discharge parameters and environmental conditions, which should be provided. Capacities for more than one set of conditions may be appropriate if the battery pack can be used for different applications. This information should be captured under “Discharge Characteristics.”

3.8 Shelf life (Also see Section 7.0)

It is common for finished cells and batteries to be stored prior to installing them in devices during the assembly process. Manufacturers often store the finished, cell-containing devices before shipping to the user. The user may also store devices prior to use.

Several factors determine shelf life of cells and the devices that contain them. For example, self-discharge reduces the capacity of the battery over time.

In addition to the cell self-discharge (see Section 5.4), devices may draw current from the cells or batteries during storage thereby reducing their capacity. This must be accounted for when determining shelf storage time limits.

Storage conditions can also have an effect on shelf life. Therefore, it is important to specify environmental conditions and the maximum storage time for individual cells, battery packs and battery powered medical devices.

Finally, the user should be made aware if rechargeable cells and batteries, or the devices that contain them, need to be periodically recharged during storage. The user also should be informed of the appropriate charging method (see Section 4.0).

4.0 DEFINING CHARGE CHARACTERISTICS AND SPECIFICATIONS

In This Section:

- General description of charge characteristics for secondary (rechargeable) cells and battery packs
- General description of methods for terminating charge
- What to specify

The following operational limits for battery charging and measurement tolerances (voltage, current, and capacity or energy) should be provided in the specification and data sheet.

4.1 Charge Limits

The charge limits below may indicate operational constraints, charging cut off limits, or an identified point where the type of charging method changes:

- Maximum charge voltage
- Maximum continuous charge current
- Maximum charging time – the maximum time that a battery should be charged.

Example: If a battery is not fully charged within 6 hours and the battery did not meet one of the other charge stop limits, then charging will terminate.

4.2 Environmental Conditions

The following may affect charging:

- Temperature range
- Relative humidity range
- Pressure external to the cell or battery

4.3 Charge Procedure

A charge procedure includes a Description of the charging current, voltage, and limits:

- Constant current: single or multiple current steps
- Constant voltage: single or multiple voltage steps
- Pulse current: transient current
- Constant current–constant voltage (CCCV): a procedure that is common for lithium ion cells and batteries. Cells or batteries are charged at a constant current to the charging voltage limit and then maintained at a constant voltage until the current decreases below a defined limit (see Charge Termination section).
- Conditions that initiate charging (voltage, discharged capacity, time)
- Definition of what constitutes over-discharge and overcharge conditions, and special procedures to follow if the battery is over-discharged or overcharged

4.4 Charge Termination

Descriptions of the methods used to terminate charge and examples of methods for different cell chemistries are:

- **Timed charge.** Charging stops after a pre-defined time – Nickel-metal hydride
- **Maximum charge voltage.** Charging stops when voltage reaches a pre-defined limit during constant current charge – lead acid, lithium ion
- **Minimum current for CCCV charge (for example, C/20 or 0.1 A for a 2 Ah cell).** Charging stops when charging current decreases below a pre-defined limit – lithium ion
- **Temperature cut off (TCO).** Charging stops when the cell or battery temperature exceeds a defined value –nickel-cadmium, nickel-metal hydride
- **Change in voltage (-ΔV).** Charging stops when a decrease in voltage from a maximum voltage level exceeds a defined value – nickel-cadmium, nickel-metal hydride
- **Change in temperature (ΔT/Δt).** Charging stops when the rate of temperature increase exceeds a defined value – nickel metal hydride
- **Maintenance charging.** Charging continues at a low rate to maintain the state of charge such as trickle and float charging – lead acid, nickel-cadmium

5.0 DEFINING DISCHARGE CHARACTERISTICS AND SPECIFICATIONS

In This Section:

- General description of discharge characteristics for secondary (rechargeable) cells and battery packs.
- What to specify.

Specification of the discharge characteristics is critical for providing the usage window of a battery and the expected performance of the battery in that window. Measurement tolerances (for example, voltage, current, and capacity or energy) should be included. Discharge characteristics and reasons for specifying are presented here.

5.1 Open-circuit voltage range upon receipt by device manufacturer (when equilibrated at specification temperature)

Provides evidence that the battery meets specification and has been handled properly.

5.2 Operating voltage range

- Provides the voltage range for the specified loads from which the cell capacity has been determined.
- Ensures that the battery should perform with intended stability within the given voltage range. Using a battery in a voltage range outside the intended specified range could result in detrimental performance (high self-discharge, chemically instability of the battery components, excessive swelling, component corrosion, lower than expected capacity, etc.).

Factors that can impact the voltage of the battery include depletion through either long-term, low-current discharge (background or quiescent load) or short-term, high-current discharge (i.e. telemetry, pulsing). In addition, the battery voltage can be influenced by temperature variation. Changes in internal resistance can affect short-term high current discharge voltage.

5.3 Deliverable capacity or energy (based on the amount of active material and the intended discharge application)

- Deliverable capacity or energy should be specified in the applicable operating voltage range at the applicable discharge rate and temperature. Capacity or energy requirements may also exist for minimum and maximum discharge rates and temperatures. Variation in capacity or energy should be specified with respect to minimum runtime and should be considered when designing cell balancing electronics for multi-cell packs. The deliverable capacity or energy provides the device manufacturer with an idea of battery longevity.
- For rechargeable batteries, the rate at which deliverable capacity or energy is reduced is a function of cycling and calendar time. The failure endpoint should be specified by the device manufacturer.

5.4 Self-discharge rate

The impact of self-discharge – the reduction of the deliverable charge of a battery as a function of time, even when the battery is not in active use – and its impact on runtime should be considered for batteries. Typically attributed to parasitic reactions within the battery, self-discharge of the

primary battery at typical shelf-temperatures and storage state-of-charge should be specified. For rechargeable batteries, the expected shelf-life before the battery or cell voltage drops below the operating voltage range should be greater than the specified battery shelf-life.

Self-discharge does not include current drain from the device (see also Section 3.8).

5.5 Maximum discharge current

The battery should be capable of supporting the required maximum discharge current drain of the device for the specified length of the drain without dropping below the required operating voltage. This should be the case even when excessive cell swelling, cell shut-down, or cell venting occur due to use of the cell at a higher current than intended The maximum discharge current must be within the current-carrying limitations of the electronic circuits. Both continuous drain as well as intermittent spikes in demand should be considered for the maximum use case.

6.0 MECHANICAL DESIGN CONSIDERATIONS

In This Section:

- Physical properties and interactions
- Safety features
- Environmental factors

The mechanical design is key to manufacturing safe and reliable cells and batteries that perform according to specifications. Component and assembly dimensions, as well as their tolerances, need to anticipate the form, fit and function of the device. Additionally, the connections between cells and from the cells or battery to the device need to be appropriately designed. Inputs to the mechanical design should consider the ways that the system responds to use conditions, environmental exposures and interactions between the components without compromising safety features.

6.1 Dimensions and Tolerances

Physical interactions between the battery, its enclosure, system components, and its use environment are important because batteries are electrochemical systems. Cells may expand and contract during normal use. Therefore, the mechanical design specifications for the battery enclosure should accommodate this expansion and contraction. For example, the individual cells in battery packs should be arranged and connected in such a way that their expansion and contraction will not cause physical damage to the cells, the pack, or the device. Similarly, for devices that use replaceable batteries, the mechanical design should reduce the likelihood that expansion would cause the battery to become lodged in the battery compartment.

6.2 Connectors, Cables and Interconnects

The quality of the electrical connection between battery and device may depend on physical properties of the connectors, such as surface area, contact force, and contact materials. The mechanical design specifications should ensure that the physical properties of the electrical connectors are adequate to prevent issues that may occur due to high contact resistance or loose and intermittent connections. Selection of contact materials should consider half-cell potentials of the mating surfaces and environmental conditions that could cause contacts to corrode during use or storage. Connectors, cables, and interconnects should be appropriately rated for voltages, currents, and temperatures that may be encountered within the devices during manufacturing, use, and storage. For replaceable batteries, the connector should be designed to meet the number of connection cycles over the expected life of the product.

The external surface of replaceable batteries should have clear polarity markings near the terminals. If the battery is connected by means of a wire harness, the connectors should be keyed in order to prevent reversed polarity connection.

6.3 Safety Considerations

The device design must not interfere with the safety features of battery cells or packs. For example, many battery types include a pressure relief mechanism that allows the cell to vent gas in order to prevent swelling or exploding during normal use or under fault conditions. If a device or its battery compartment is sealed to prevent fluid ingress, vented gases may create excessive pressure within

the device or battery compartment. This could lead to a hazardous situation or cause damage to the device. The device's mechanical design should include a means of relieving pressure caused by gases vented from the battery.

Depending on the battery type, there may be other safety features that may require special consideration in the mechanical design of the device as described in Section 9; it may be necessary to consult the cell or pack manufacturer in order to verify that those features will not be compromised by the device design. Consider charging, discharging, shock and vibration, and environmental factors when evaluating the interaction between the battery and attributes of the device mechanical design.

6.4 Shock and Vibration

The mechanical design of the device and its battery and battery compartment should be able to withstand the shock and vibration forces that are likely to be encountered not only in the intended use environment(s), but also in other reasonably foreseeable environments such as shipping). It is usually worthwhile to use applicable standards from IEC and/or ASTM to establish appropriate design requirements for the shock and vibration tolerance of cells and packs. See Annex A for a list of standards that may be applicable to your application.

6.5 Thermal Management

As electrochemical systems, batteries are affected by the environmental temperature. Within a device, heat may be generated by several sources, including system components such as an inefficient AC-DC converter and the battery itself. Depending on the particular battery type and expected use environment, it may be necessary for the device's mechanical design to include features to manage battery temperature in order to permit safe operation and to optimize battery service life. In addition to any risk controls required for protecting the battery from over-current, over-temperature, or other faults, design features such as heat sinks, fans, and vents can be used to regulate the battery temperature under normal use conditions.

Thermal management systems and their components are subject to failure just like any other component. These potential failure modes should be carefully evaluated during the design of the device. For example, a worn or defective bearing in an exhaust fan could prevent it from effectively regulating the battery temperature. If the system is unable to detect the failure and respond appropriately, then the battery may be at risk of a temperature-related failure.

6.6 Ingress Protection

Depending on the medical device, the battery may be exposed to various foreign objects (for example, fingers, screws, dust) and fluids. Therefore, it is important that the mechanical enclosure of the battery be designed with the appropriate level of ingress protection commensurate with the expected use environment. Ingress protection is typically rated for both particulates and fluids with separate distinctions. It is recommended to reference IEC standard 60529 (IP Code, International Protection Marking) for the appropriate IP ratings and test methods. Ensure that ingress protection does not prevent the battery from venting properly.

7.0 DEFINING SERVICE LIFE AND RELIABILITY

In This Section:

- Service life factors
- Reliability factors
- Short-circuit causes

The medical device manufacturer is responsible for providing service life and reliability information for the battery used in the medical device regardless of whether or not the battery was developed/manufactured by the medical device manufacturer or purchased from another supplier. The sections below list some factors to consider when providing service life and reliability information.

7.1 Service Life – Factors to Consider:

At a high level, the service life information considerations should cover all expected use conditions and environments through the full life of the battery; from creation through end-of-service and disposal. Some factors to consider include:

- **Battery Shelf Life**– significant battery aging and degradation may occur between the time the battery is manufactured and when it is put into use or installed in the medical device. The medical device manufacturer should be cognizant of the potential duration of time the battery spends in inventory, transport and on customer's shelves prior to use. Degradation can occur in the form of loss of capacity or increased impedance over time and can be further exacerbated by the environmental condition experienced during transport or storage (for example, uncontrolled temperature in shipping containers, vehicles, warehouses, etc.). For primary batteries, capacity used after device-hookup but prior to going into service, should be also considered.
- **Variable Current Drain During Various Stages of Service Life** – Special considerations should be made for atypical operating modes of the medical device that may result in atypical current drain. For example, there may be implanted cardiac devices with primary cells that operate a radio for communication with external equipment. In this case the current drain is much higher than typical use. In this example, the medical device manufacturer should factor in the expected amount of time the radio is turned on over the service life of the device and account for the additional drain.
- **Temperature Variations over the Service Life** – A comprehensive assessment of all temperature conditions over the service life should be conducted and factored into the service life information. One area that is often overlooked is the temperature experienced during the manufacturing process of the battery and device. One example is localized welding of the device assembly can translate unwanted heat to the battery. Another example is in the sterilization of the device where the dwell temperature in the sterilization process is too high resulting in degradation of the battery. For example, an implanted device will be in a controlled environment of approximately 37°C, but other medical equipment may be at room temperature or outdoor environmental temperature. Aging reactions may include self-discharge (time-dependent capacity loss) and time-dependent impedance increase, or capacity fade for rechargeable batteries.

- **Capacity Fade for Rechargeable Batteries** – The charge voltage and depth of discharge for a rechargeable battery can affect the service life of the battery. Typically, shallower depths of discharge and lower charge voltages (undercharging) are favorable for improved cycle life as these conditions usually result in lower capacity fade. In contrast, rechargeable batteries that are continuously discharged to full depletion and charged to maximum capacity usually experience an increase in capacity fade and reduction in cycle life. Other factors include the charge rate used and the temperature during charge.

7.2 Reliability Factors to Consider

Reliability includes both component and system level analysis.

- **End of Battery Service –** For rechargeable batteries, consider a battery replacement indicator to provide the user with an alert at or before the end of its service life.
- **Battery Charge Level –** Consider a battery charge level indicator to alert the user to battery charge level. For rechargeable batteries, consider combining charge level with an indicator to alert the user when the battery needs to be recharged.
- **Battery Impedance or DC Resistance** – Evaluate the impact of battery impedance on device function at various device current conditions (battery impedance may be current, temperature, state of charge, and test signal frequency dependent).
- **Battery Failure Modes and the Probability of Occurrence** – Consider safety and performance issues associated with internal short circuit (see Section 7.3 for more information), high impedance, loss of internal contact, lithium deposition (for rechargeables), and corrosion of components, the package, or the case, etc.
- **Packaging Integrity or Hermeticity** – Determine conditions under which the battery must remain free of electrolytes, or vapor leaks that may damage nearby device components. If the battery case is exposed to the outside environment, leaking electrolyte may cause harm to the user or may increase battery impedance prematurely.
- **Dimensional Stability** – Consider whether changes in battery dimensions such as swelling would damage other device components or weaken connections.
- **Device Assembly Processes** – Assess the impact of device manufacturing processes on the battery (for example, high temperature processes, welding, handling, contaminates, etc.).

7.3 Internal Short Circuits

One cause of a cell or battery failure is an internal short circuit. These are the result of an unintended direct electrical connection between the anode and cathode within a cell. The failure mode of a cell with an internal short circuit is dependent on the type and extent of contact between the anode and cathode, the power capability and stored energy of the cell, the safety features of the cell or battery, and the environmental conditions. Internal short circuits may be slight (soft short circuits or high impedance short circuits), resulting in faster depletion of the battery, or they may be extensive (hard short circuits or low impedance short circuits), leading to catastrophic failures such as explosion and fire. Generally these failures are latent, taking some time to develop, and they can be unpredictable.

Here are some causes of internal short circuits that should be mitigated:

- **Overdischarge:** Lithium ion batteries typically use a copper foil current collector for the anode. If a lithium ion cell is overdischarged, the copper foil could become oxidized forming copper ions. When the cell is recharged, these copper ions may plate on the negative electrode forming dendrites, which could eventually grow long enough to create a short circuit condition between the positive and negative electrodes.
- **Overcharge:** For lithium ion cells, lithium metal may plate on the carbon anode if 1) a cell is overcharged beyond the maximum charge voltage, 2) a cell is charged for a longer period of time than required for a full charge, 3) a cell is charged too rapidly or 4) a cell is charged at low temperatures. Lithium metal tends to form dendrites as it plates. If these dendrites continue to grow, they could make a direct connection between the positive and negative, causing an internal short circuit.
- **Foreign Material (FM):** FM can be introduced into a cell or battery during the assembly process. Conductive and nonconductive materials may be considered FM. Manufacturing controls are the best way to minimize the possibility of introducing harmful FM into a cell or battery. FM may puncture the separator in a cell and allow a direct connection between the anode and cathode. Another failure mechanism can occur by the combination of FM type and location. For example, copper in contact with the cathode could oxidize the metal FM, forming metal ions. The metal ions may dissolve in the electrolyte, diffuse to the anode, and plate there. If the plated metal forms dendrites that grow to a sufficient size, a direct connection between the anode and cathode may form, causing an internal short circuit.

  Standard IEC 62133 Section 8.3.9 includes methods to test cell safety when FM is present in the cell.
- **Mechanical Damage:** Mechanical damage may be caused by denting, crushing and piercing the cell case. When mechanical damage is severe enough to force direct contact between the anode and cathode, an internal short circuit will occur.
- **Thermal Damage:** Excessive heating of a cell may cause the separator to melt and shrink. This would allow the anode and cathode to come into direct contact causing an internal short circuit. For lithium primary batteries, heating in excess of 180°C results in the lithium metal anode melting. The liquid lithium that forms may then flow throughout the cell and contact the cathode producing an internal short circuit.
- **Lithium Clusters:** In rare instances, lithium primary batteries designed to power implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators may form lithium metal clusters within the battery. If these clusters grow in a suitable location and become sufficiently large, a short circuit between the anode and cathode may form. If this occurs, the battery will rapidly deplete and result in a reduction of device function.

8.0 SMART BATTERY TECHNOLOGIES AND INTERFACES

In This Section:

- Architecture
- Electronics
- Design considerations

Smart battery technology is a term for specialized electrical components with specific functionality for battery management and battery safety. The level of sophistication of these technologies has improved over the past decade and continues to evolve with increasing battery management functionality and safety. The evolution of smart battery technologies parallels well with the advancements in battery chemistry resulting in increases in battery capacity and energy density. Increases in battery capacity and energy density allow for smaller and longer lasting batteries but this also heightens the awareness and concern for battery safety issues including fire or explosion. As such, the majority of batteries today utilize some level of smart battery technology and battery safety and transportation standards (such as IEC 62133, UL 2054, UN 38.3) help ensure that these technologies are implemented correctly and adequately for compliance to their respective safety requirements.

Smart battery technology can be divided into three functional categories including:

- Gas Gauge (or Fuel Gauge)
- Battery Protection
- Battery Charging

Historically these functions were initially offered as separate electrical components (for example, gas gauge integrated circuit (IC), battery protection IC, and battery charging IC). But with the advancements in technology and integration today, there are components that contain all three functions in a single package. When incorporating smart battery technology into a design, almost all of these components require supporting electrical components which may include transistors, resistors, capacitors and diodes. A careful review of the design implementation, component tolerances, fault tolerance, and electrical interfaces is required.

When incorporating these technologies in batteries for medical devices, all of the standard design practices for batteries apply, however, medical device batteries may have an added level of safety especially if the battery power provided has direct impact on patient safety. All of the risks and risk mitigations for battery safety and user safety should be well documented in risk management documentation.

A comprehensive specification of the medical device battery should be provided and include a high level battery architecture and system block diagram supported by implementation details for gas gauge, protection, and electrical interfaces as outlined below.

8.1 Smart Battery Architecture and System Block Diagram

A high level description of the battery architecture, how the battery is used and how it interfaces with the medical device should be included in the specification. Consider including the following content:

- Battery block diagram describing the functional blocks of the battery, smart battery technologies used, and the interface to the cells.
- System block diagram describing how the smart battery interfaces with the medical device including power outputs, status lines, and communication lines as applicable.
- Description (if required) of the means of fault tolerance or redundancy in the case of a single battery failure.
- Description of the battery power management system explaining the battery charge and battery replacement procedures.

8.2 Gas Gauge Electronics

Gas gauge electronics refer to dedicated electrical components used to provide the battery's state of charge and other information. Gas gauge electronics have many features that are configurable depending on the application. A description of how the gas gauge is configured and used should be provided. Consider including the following content:

- Describe the gas gauge method used to determine state of charge, such as coulomb counting, internal impedance, and voltage.
- Describe how cycle counting is implemented including what a cycle is defined as (for example, cumulative 2000 mAh discharged).
- Describe if battery temperature is monitored and if it is incorporated for charge, gas gauging, or protection.
- Describe how gas gauge accuracy is maintained (for example, calibration procedure, self-calibration).
- Parameters specific to chemistry and battery design such as voltage and internal resistance.
- Conditions that place the device in sleep mode or shut-off.
- Cell balancing functions that passively or actively attempt to equalize individual cell states of charge in a battery pack.
- Monitoring of individual cell voltage in a battery pack.

8.3 Protection Electronics

Protection electronics refer to dedicated electrical components used to protect the battery from unsafe operating conditions. The specification should provide a description of the implementation of protection electronics. Consider including the following content:

- Description of the overvoltage protection and thresholds used to prevent charging beyond the defined charge voltage limit.
- Description of the undervoltage protection and thresholds used to prevent discharging beyond the defined low operating voltage limit.
- Description of the short circuit and overcurrent protection and thresholds used to prevent cell damage in hazardous transient conditions.

- Description of the overtemperature protection to prevent operation at unsafe temperatures.

8.4 Charge Electronics

There are generally two different architectural approaches to battery charging management. The first is having the charge function and control resident in a separate device or battery charger such that the charge algorithm and control reside in the battery charger. The second approach is having the charge algorithm and control reside in the battery itself such that the battery will manage its charge whenever it is connected to a power source. Wireless charging is a variant that involves the transfer of energy from a transmit coil from an external charging device to a receive coil resident in the battery for battery charging. In any case, the charge algorithm and conditions should be specified as recommended in section 4.0, Defining Charge Characteristics and Specifications.

8.5 Smart Battery – User Interface

Perhaps the most important user information to provide with respect to the battery is its state of charge. This is a measure of how much battery charge is available for use whether it has been sitting on a shelf for months or is actively discharging and powering the medical device. (See Section 10.3 for more detailed information).

8.6 Electromagnetic Compatibility (EMC)

Electrical medical equipment should be designed to ensure that it does not radiate excessive electromagnetic emissions that interfere with the operation of other nearby electronic equipment, and to ensure that the medical equipment can operate safely and as intended in the presence of electromagnetic emissions from other nearby electronic equipment.

Electrical medical equipment should be designed for use in its intended electromagnetic environment as described in IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. These electromagnetic environments include professional healthcare facilities, the home healthcare environment, and special environments, such as military, industrial, and shielded rooms. The test methods and severity of the tests depend upon the intended electromagnetic environment of use. Typical tests include limits on the electromagnetic emissions generated by the medical device and protection of the medical device (immunity) from outside electromagnetic sources, such as electro static discharge (ESD) and other electromagnetic emissions sources, including cell phones, industrial equipment, and power lines.

Medical devices intended to be used in airline travel for either commercial airlines or medical transport should be designed to comply with the applicable sections of RTCA-DO 160 (latest edition) Environmental Conditions and Test Procedures for Airborne Equipment.

For both of the above-mentioned standards, medical devices containing batteries are tested when AC powered (if applicable) and again when powered by battery only. Depending on the application, EMC tests may be conducted at the individual battery level as well as the system level. Batteries can be susceptible to electro static discharge when handled by the user and, therefore, should be tested to the ESD requirements in IEC 60601-1-2.

Before, during, and after EMC tests, medical devices are expected to remain safe and provide essential performance (perform as intended).

9.0 SAFETY FEATURES

In This Section:

- Battery Safety
- Interface conditions
- Medical device considerations

Battery safety in medical devices is a multifaceted conversation. The manufacturer must not only consider the hazards posed by the batteries, but also how that energy being stored is transferred to the end product and the risks posed by not having energy available.

The first topic is the safety of the battery itself. It will contain references to existing prescriptive requirements via a list of applicable standards. It will also contain additional risk considerations not due to the nature of batteries, but rather the unique nature of medical devices.

The second topic is the interface conditions that exist between the battery and the medical device. These are not specific to either the battery or the medical device, but special consideration is needed to relate how the energy is transferred.

The final topic of discussion is considerations for the medical device powered by a battery. There are many considerations when it comes to the safety of medical devices—battery powered or otherwise—and this section is not intended to cover all of them. Rather, the discussion shall be limited to general considerations and examples.

9.1 Battery Safety

Regardless of the application, there are some common hazards related to the battery itself. Battery safety requirements can be found in existing standards; a list of standards can be found in Annex A of this document. However, other standards may be appropriate.

Standards guiding battery safety testing are not generally applicable to batteries designed for implantable medical devices. However, they must comply with transportation regulations based on UN Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria, Section 38.3. These tests cover many of the same tests and test objectives as the battery safety standards.

While the existing standards address hazards known to exist at levels deemed to be unacceptable, there may be other risks that are generally accepted by the battery community but not the medical device manufacturer. As such, it is important for the medical device manufacturer to recognize that compliance to existing battery safety standards may not satisfactorily address all risks associated with batteries used in medical devices.

The discussion of specific risks to be considered can be divided into at least two distinct sections:1) risks specific to implantable medical devices, and 2) risks specific to devices used externally.

Hazards relevant to battery powered implantable devices that may require special attention include the possibility of rapid expansion and elevated temperatures. For example, a common cause of this hazard is a short circuit event. The source of the short circuit may derive from a fault in the device electronic circuits or within the battery. Because the risk of electrolyte leakage from a battery in a fully implantable medical device is intolerable, these batteries are hermetically sealed and do not have a vent. Rapid depletion of a sealed battery can lead to expansion of the case. In the worst

cases, release of electrolyte leakage into the device may occur if the cell becomes unsealed due to excessive case swelling. Elevated temperatures produced within the battery of an implanted device may dissipate heat to the device can. If the temperature of the device can is sufficiently high, tissue damage may occur.

Expansion of the case and higher temperatures may also occur during normal operation for both primary and rechargeable batteries depending on the chemistry, mechanical design, and charging and discharging conditions.

For batteries used in external applications, risks associated with venting are worth consideration. External batteries often include a vent to prevent rapid deconstruction. This venting is often accompanied by battery electrolyte, which may or may not be caustic or flammable. The venting of the electrolyte is often a terminal event and the battery will no longer function. However, the venting of gas during the typical life cycle of some battery chemistries is common and worth noting within the risk file.

9.2 Interface Conditions

The concept of interface conditions is not meant to be specifically limited to electrical connections that exist between the battery and the end product. Rather, it is meant to be inclusive of those risks that are neither specific to the battery, nor the medical device. These are generally related to how the battery interacts with the medical device.

For battery powered medical devices that ship without batteries and for which customers must provide suitable batteries (typically non-rechargeable), device manufacturers should provide sufficient descriptions of the required battery types. This is most often in the form of a common battery form factor. For instance a device manufacturer may specify AA batteries as being required, though the manufacturer should not assume that all AA batteries will be alkaline batteries with a typical voltage of 1.5 volts per cell. In fact the voltage of an AA battery, form factor only, may range from 1.2 volts per cell to as much as 4.2 volts (in the case of lithium ion) per cell. The manufacturer should consider to what level of specificity the battery type should be defined. A voltage range of 1.2 to 4.2 volts per cell may be tolerable, and in this case a simple declaration of AA would then be sufficient. The other extreme is where the performance and safety of the device is heavily reliant on the discharge characteristics (see discharge characteristics section) and may need to be strictly defined.

In situations where the expected service life of a rechargeable battery is less than the expected service life of the medical device, acceptable replacement battery types and appropriate replacement practices must be defined. Just as for primary cell replacement described earlier, the manufacturer should consider providing removal and installation instructions as well as a sufficient description of battery form factor, size, chemistry, and operating voltage range. If possible, identifying battery suppliers and model numbers may reduce the use of improper batteries. Additionally, the charge mechanism characteristics should be considered, particularly if the equipment manufacturer does not provide a charger.

Additionally, batteries often require safety measures that may include current interrupt devices (CIDs) such as fuses, positive temperature coefficient devices (PTCs), temperature monitors, and pressure switches. In these cases the manufacturer should consider whether these are integral to the rechargeable battery or battery pack, or if additional requirements need to be placed on replacement batteries in order to maintain safety and proper performance.

In certain circumstances the manufacturer may choose to implement or require what may be referred to as smart battery characteristics within an external or integral battery pack. For purposes of this discussion, a smart battery is considered a battery that includes self-monitoring circuitry. Whether it is monitoring capacity or battery health, the manufacturer should consider the importance of the accuracy of the information relayed by the smart battery. Regardless of the information that is being relayed to the user or the medical equipment itself, it is assumed that certain information prompts a certain response. In those cases the response may or may not be critical and should be assessed through the manufacturer's risk management process.

9.3 Medical device considerations

The safety of battery operated medical devices is covered with the IEC 60601-1 standard, EN 45502-2 series and ISO 14708 series.

In addition to those requirements specific to batteries, IEC 60601-1 discusses the concept of essential performance. Strictly defined, essential performance [1] is performance of a clinical function unrelated to basic safety, and where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. However, for a device that is clinical in nature, the ability for that device to continue functioning without AC mains power might also be considered a clinical function.

Essential performance is best understood as the ability of a medical device to monitor or provide therapy as intended; perform at a reduced level, but at an acceptable residual risk level; or else provide an indication to the patient or operator that there is a malfunction. Essential performance criteria for medical devices are specified in the particular device standards to IEC 60601-1 and may be determined by the manufacturer in the risk management file as indicated in ISO 14971:2007 Application of risk management to medical devices. It is suggested that considering essential performance, as driven by the manufacturer's risk file, be the method of addressing hazards specific to medical devices employing batteries.

[1] Definition 3.27 of IEC 60601-1 Edition 3.1

10.0 BATTERY MANAGEMENT

In This Section:

- Labeling considerations
- Preventing incorrect replacement
- Battery Indicators
- Storage and disposal

Proper battery management is essential for safe operation of battery powered medical devices. The device manufacturer should provide sufficient information to ensure that the operator is able to perform any necessary battery management tasks correctly.

10.1 Labeling

Labeling for battery powered medical devices should support basic information the user needs to properly operate the device and address any residual risks that are not adequately mitigated by other means.

The following subsections show some topics commonly covered by labeling, but are not intended to be an exhaustive list for all medical products.

The complete requirements for labeling can be found in the applicable standards shown in the Annex.

10.1.1 Instructions for Use

Depending upon the type of battery used, and to ensure that the user has the appropriate information to determine safe use, the labeling and the instructions for use should consider the following information:

- Acceptable use environments, for example for home or clinical settings
- Safe environmental conditions, for example temperature, moisture, and pressure
- For secondary batteries, instructions for proper charging
- For user-replaceable batteries, instructions for proper battery replacement
- Replacement timing, if it carries risk to the patient or operator
- Monitoring frequency
- Proper handling and storage (see Section 11)
- Travel considerations
- Instructions for the proper disposal of the batteries

10.1.2 Warnings and Precautions

Warnings and precautions are generally developed in response to residual risk identified in the risk assessment process and as a result of experience with use of similar products or predicates.

- Environmental interactions (temperature, moisture, and pressure)
- Exposure to external sources of energy from medical devices such as electrocautery devices, cardiac defibrillation, MRI, X-ray, and ultrasound or non-medical equipment such as electric generators, and welders
- Warnings for mishandling (such as burn, fire, explosion)
- Actions to avoid (crush, disassemble, dispose of in fire)
- Warnings not to recharge primary batteries
- Warnings to keep batteries out of reach of children
- For user-accessible coin cell batteries, a warning to prevent swallowing

10.1.3 Identification and Traceability

Identifying information that is critical for battery complaint analysis should be available. Additional information may be required by applicable standards.

- The manufacturer's name, trade name or similar
- Model or catalog number
- Date of manufacture or similar

10.2 User-Replaceable Batteries

For devices with batteries that are intended to be replaced by the user, the manufacturer should design products so that incorrect batteries cannot be used. These should include designs with lockout mechanisms that will prevent incorrect polarity of connection by mechanical means. The manufacturer should consider using smart battery technology that will alert the user when an incorrect battery has been inserted.

The equipment manufacturer should consider the hazards caused by the incorrect battery replacement by the application of ISO 14971:2007 Application of risk management to medical devices.

These include hazards to the patient and operator if incorrect or sub-substandard batteries are used. An example from IEC 60601-1 3rd edition is "where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained or informed personnel could result in a HAZARD (such as excessive temperatures, fire or explosion) shall be given."

The manufacturer should include information for the safe use of batteries including battery specifications, battery warranty, battery replacement, and battery management in the instructions for use. The patient or operator should be given instructions explaining battery replacement and the safe use of batteries.

10.3 Battery Indicators

The manufacturer of a battery powered medical device should determine which battery indicators are needed based on conclusions of the risk assessment. The information provided by the indicator(s) should be commensurate with the risk posed to the user to ensure safety of the patient

and user. The manufacturer should provide justification that the indicator is sufficient to mitigate risks associated with battery management. If the loss of battery power is determined to pose an insignificant risk to the user, indicators may not be necessary.

In many cases, particular and collateral standards to IEC 60601-1 contain requirements for battery indicators. These include battery charging status, low battery indicators, battery capacity remaining, and switchover from AC mains to battery power.

10.3.1 State of Charge

Perhaps the most important user information with respect to the battery is its State of Charge (SOC). This is a measure of how much remaining charge is available for use by the device. For rechargeable batteries, state of charge also indicates how much charging time the battery needs to be fully charged.

State of charge can be communicated to the user in a number of ways, such as a visual gauge, amount of battery life remaining given as a percentage of available capacity or the time to the end of the battery service life, or even with simple LED indicators. Alarms in the form of audio, visual, or vibratory may be used to indicate when an action is required.

For systems that display an aggregate state of charge of multiple batteries, a description of how information from the batteries is summed, processed, and translated is recommended.

If a battery charge indicator is deemed necessary, it should provide, at minimum, the following information to the user:

- Indicator for the remaining charge available for use.
- Secondary batteries, indicator that a recharge is necessary.

The accuracy with which the system may report remaining battery life, and the labeling describing the expected battery life should be driven by user needs and the risk to the patient and operator. If the device is life supporting and an unanticipated loss of device function could result in serious injury or death to a patient or operator, then the requirements for projecting battery life must be accurate and take into consideration all known factors that impact the projected battery life. For medical devices that are of a lesser risk, the rigor and validation of the projected battery life should be commensurate with the risk to the patient or operator.

10.3.2 End of Useful Service Life

A battery should be taken out of service when it reaches the end of its useful service life.

For primary batteries, end of useful service life corresponds to the state of charge at which the battery is no longer able to provide sufficient power to operate the device safely. It is typically specified as a minimum useful voltage or maximum useful capacity.

For secondary batteries, end of service life is usually defined as the point at which the battery can no longer meet its performance specifications. It is often specified as a maximum limit for the number of recharge cycles.

Indicators should provide the necessary information for enabling the user to act prior to reaching an unsafe operating condition. If a battery replacement indicator is deemed necessary, it should provide, at minimum, the following information to the user:

- Primary battery is nearing the end of its useable life, and it should be taken out of service.
- Secondary battery should be permanently removed from service due to such conditions as cycle count limit being exceeded, the battery being past the expiration date, and measured performance being too low.
- Primary and secondary batteries, battery fault.

The following should be considered if an end of service life indicator is deemed necessary:

- Degradation in battery performance has impact on safety
- Impact of the applied load on cell voltage and impedance changes that occur over the life of the cell
- Maximum recharge cycle count for rechargeable batteries
- Total duration of use
- Impacts of use environment on battery discharge

10.4 Storage Considerations

Refer to Section 11.

10.5 Battery Disposal

Batteries should be disposed of properly according to local regulations. If necessary the battery or medical device manufacturer can be contacted for disposal instructions.

11.0 ENVIRONMENTAL CONSIDERATIONS AND HANDLING PRACTICES

In This Section:

- Temperature limitations
- Storage conditions
- Safe handling

Operating and storage temperatures, storage time and safe battery handling are important considerations for battery powered medical device manufacturers and users.

11.1 Operating Temperature Limitations

Batteries are designed to operate over wide temperature ranges. However, there are limitations to charging secondary batteries at the extreme high and low ends of the operating temperature range.

It is important that the cell and battery operating temperature specifications are matched with the medical device's intended environments. These can include environmentally controlled areas such as professional health settings (hospital, physician's offices, and surgical centers, and environmentally uncontrolled areas such as home care settings and transport.

Batteries are to be designed with the appropriate level of overtemperature protection to ensure operation is within the temperature, voltage, and current limits specified by the cell manufacturer.

Medical device manufacturers should ensure that specifications for charging circuits match those of the battery manufacturer in terms of temperature, voltage, and current in order for the batteries to operate safely.

11.2 Storage Temperature Limitations

Storage conditions for batteries depend on the active chemicals used in the cells. Self-discharge or chemical decomposition can occur if not stored properly. It is important that the cell and battery storage specifications are matched with the intended environment of use of the medical device. These would include air, land or sea transport, storage when installed in a device, and shelf storage. It is best to consult the cell and battery manufacturer for guidance.

The general guidelines below are based on cell and battery chemistry type:

11.2.1 Primary Cells

Primary cells cannot be recharged and any loss of capacity is permanent. Therefore, it is important to follow the manufacturer's recommended storage specification

11.2.2 Secondary (Rechargeable) Cells

Depending on the chemistry type, secondary batteries should be stored in a charged condition. Typically, lead acid, nickel cadmium, and nickel metal hydride are stored fully charged, whereas lithium ion is stored with a partial charge. After prolonged storage, secondary batteries will most likely need recharging before use as specified by the battery manufacturer.

11.3 Maximum storage time prior to use

Maximum storage time is dependent on the battery chemistry and type. General guidelines (see batteryuniversity.com) show that primary alkaline and primary lithium batteries can be stored up to 10 years, nickel-based batteries up to five years, and secondary lithium ion up to three years when discharged to 30% to 50% capacity. Refer to the battery manufacturer guidelines for storage guidelines. Storage requirements and the associated labeling disclosures also can be found in the applicable battery standards included in Annex A such as IEC 62133, IEC 62281, and IEC 60960.

11.4 Safe handling of batteries

In general, batteries should be handled with care to avoid short-circuiting or other damage that can lead to leakage, rupture, explosion or fire. During transport it is important that the battery packaging be designed to prevent mechanical damage. The packaging should be designed to prevent crushing or unintentional electrical short circuit and corrosion of the terminals which can result in leakage, venting, rupture, explosion or fire.

During transport of batteries it is recommended to use the original packaging or packaging that complies with the requirements of the relevant dangerous goods regulation. It is important that the packaging comply with the relevant dangerous goods regulations when batteries are shipped to customers and also when shipped back from the customer to the manufacturer for return or repair. References to Dangerous goods regulations are included in Annex A. These include IEC 62881; United Nations recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria ST/SG/AC.10/11/Rev.5 Section 38.3 2009; 2013-2014 edition of ICAO technical instruction for the Safe Transport of Dangerous Goods (DGR); and the latest edition of IATA Dangerous Goods Regulations (DGR).

11.5 Air Transportation

In April 2016, an addendum to the ICAO regulations was issued to limit the state of charge for lithium ion batteries to a maximum of 30% when shipped separately from the device. The requirement is not applicable to cells or batteries shipped with equipment or contained in the equipment.

As noted by the Rechargeable Battery Association (PRBA) there is no single method to estimating the state of charge (SOC) of a lithium battery or cell (see prba.org white paper titled “State of Charge Lithium Ion Batteries”). The PRBA recommends checking with the cell or battery manufacturer to determine their method of implementing a 30% SOC policy or developing an internal procedure that is acceptable to regulators and airlines. The PRBA also encourages the use of a fuel gauge to estimate SOC. The manufacturer should ensure that the manner in which the battery is discharged to 30% SOC of charge does not negatively impact the performance of the battery.

12.0 MANUFACTURING PROCESS CONTROLS

In This Section:

- Off-the-Shelf Considerations
- QA and Material Controls
- In-Process Controls and Environmental Controls

Medical device manufacturers should assess the need for manufacturing process controls and supply chain controls to ensure batteries safely and reliably meet specifications in the devices' intended use environments. Device manufacturers should determine the appropriate level of rigor for controls commensurate with levels of risk. The selection of appropriate controls is often aided by the use of risk management tools, such as design and process Failure Modes and Effects Analysis (FMEAs). At a minimum, the manufacturing and supply chain controls should address any critical quality attributes identified during the risk management process.

The particular controls that are appropriate for a given device depend largely on the risk profile of that device and the level of quality and reliability required from the battery. For example, the manufacturer of a life-sustaining device, such as an implantable defibrillator, should consider a combination of material controls, in-process controls, inspections, functional tests, and environmental controls to mitigate the risk of patient harm due to a battery failure from manufacturing defects.

12.1 Commercial Off-the-Shelf Batteries

For devices that use off-the-shelf batteries from commercial retailers, device manufacturers may have limited opportunities for manufacturing controls. In these cases, device manufacturers should determine the extent to which safety and efficacy of the devices are impacted by the users' selection of particular makes and models of batteries. If device labeling recommends particular brands or models of retail batteries, then it may be prudent for device manufacturers to periodically reassess technical and quality attributes in order to ensure that the recommended batteries are still suitable.

12.2 Incoming Quality Assurance and Material Controls

If a device manufacturer is part of the battery supply chain, then there is an opportunity to implement Incoming Quality Assurance and Material Controls to ensure that batteries and battery components meet the required specifications for safe and effective use in the device. Depending on the particular needs, these types of controls can range from contracts and certifications to inspection and testing. In many cases, the device manufacturer may require the supplier to provide some form of attestation, such as a certificate of compliance or certificate of analysis, with each shipment to show that it meets the required specifications. To supplement the documentation-based controls, device manufacturers may also consider subjecting incoming materials to inspection and testing before acceptance into inventory. The appropriate level of incoming inspection and testing is usually based on risk and is focused primarily on critical quality attributes.

12.3 In-Process Controls

For custom or semicustom batteries that are manufactured to the device manufacturer's particular specifications, the device manufacturer should ensure that appropriate controls are implemented

throughout the manufacturing process. Controls vary by application and chemistry, but may include in-process variables such as dimensions, component weights, and chemical composition. A firm that designs and manufactures battery cells or packs needs to have the expertise to select the proper in-process variables for consistent product quality.

12.4 Environmental Controls

Batteries are usually sensitive to environmental conditions, namely temperature and humidity. If the device manufacturer needs to store batteries or devices that contain batteries, it may be necessary to implement environmental controls for manufacturing and warehousing facilities to reduce or prevent degradation during storage.

13.0 STANDARDS AND REGULATIONS COMPLIANCE

In This Section:

- Sources for Standards and regulations

Cells and batteries should comply with the applicable national and international standards for the chemistry and type. Typically, safety agency approvals such as UL, CSA, and TUV are required for cells and batteries. Standards include testing and evaluation for operating performance, safety from fault conditions, environmental tests, mechanical tests, and requirements for labeling and instructions for use. A list of battery standards is shown in Annex A.

Additional battery requirements are specified for medical devices containing batteries. These requirements can be found in the applicable medical device standards. Requirements in medical device standards include battery ventilation, installation, short circuit protection, battery status indicators, and additional requirements for labeling and instructions for use. Medical devices standards are typically from the IEC 60601-1 series.

14.0 LABELING REQUIREMENTS

In This Section:

- Sources and examples for labeling requirements

The standards and regulations described in Section 13 and listed in Annex A contain the labeling requirements for cells, batteries, and medical devices containing batteries. These include requirements for the cell and battery labels, medical device labels, instructions for use, and packaging labels.

The following are examples of information to be provided:

- Battery type identifier
- Manufacturer and manufacturing date or serial number
- Environmental conditions for operation and storage
- Instructions for installation to ensure proper orientation
- Instructions for safe operation of the battery
- Instructions on charging and discharge
- Instructions on replacement and disposal
- Human factors guidance should be observed to ensure that the user understands the labeling.

ANNEX A
Standards and Regulations

Cells and batteries

- IEC 60086-1 Primary batteries – Part 1: General
- IEC 60086-4 Primary batteries – Part 4: Safety of lithium batteries
- IEC 60086-5 Primary batteries - Part 5: Safety of batteries with aqueous electrolyte
- IEC 60529 Degrees of Protection Provided by Enclosures (IP Code)
- IEC 61056-1 General purpose lead-acid batteries (valve-regulated types) - Part 1: General requirements, functional characteristics - Methods of test
- IEC 61951-1 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Portable sealed rechargeable single cells – Part 1: Nickel-cadmium
- IEC 61951-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Portable sealed rechargeable single cells – Part 2: Nickel-metal hydride
- IEC 61960 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Secondary lithium cells and batteries for portable applications
- IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- IEC 62281 Safety of primary and secondary lithium cells and batteries during transport
- UL 2054 2nd Edition household and commercial batteries
- UL 1642 5th Edition lithium batteries
- United Nations recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria ST/SG/AC.10/11/Rev.5 Section 38.3 2009
- 2013-2014 edition of ICAO technical instruction for the Safe Transport of Dangerous Goods (DGR)
- IATA Dangerous Goods Regulations (DGR)
- IEEE 1725 Standard for Rechargeable Batteries for Cellular Telephones (although the standard covers cellphone batteries, its requirements are applicable to all lithium ion cells and it has the support of major suppliers of lithium ion cells)

Medical Devices

- EN 45502-2 (series) Active implantable medical devices
- IEC 60601-1 Edition 3.1 (applicable sections) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Note: IEC/ISO particular and collateral standards to IEC 60601-1 also contain requirements for cells and batteries

- ISO 14078 (series) Implants for surgery – Active implantable medical devices
- ISO 14971:2007 Application of risk management to medical devices

Environmental

- IEC 60068-2-62007 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
- IEC 60068-2-27:2008 Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock
- IEC 60068-2-31:2008 Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens