CBR Position Statement on Including Medical Device Batteries in Battery Recycling Legislation

The Corporation for Battery Recycling (CBR) is a national leader in efforts to promote the recycling of primary batteries. Recognizing that without a legal framework, those responsible for introducing batteries into the marketplace may not voluntarily accept financial responsibility for end of life management, CBR, in conjunction with the entire battery industry, has developed a model bill to promote battery recycling legislation for all batteries, both primary and rechargeable. The bill reflects a series of stakeholder engagements over a period of several years, and was carefully crafted to reflect the fundamental tenets CBR has identified as crucial to an effective and fair battery recycling framework. Such legislation must result in a program that:

- Has a positive impact on the environment.
- Is industry led and managed.
- Fairly shares responsibility so that recycling programs are financially sustainable
- Assures a level competitive playing field so that all companies that sell or introduce batteries into the marketplace contribute to the cost of recycling batteries.
- Is nationally harmonized.
- Safeguards consumers and workers tasked with collecting and recycling spent batteries.

All batteries that are likely to end up in battery collection programs, including batteries sold in or with products like medical devices, must be expressly covered in battery recycling legislation. Any exceptions or exemptions should be narrowly limited to instances where batteries are not easily removable or, with respect to medical devices, instances where a device containing a battery might be contaminated with blood or bodily fluids and pose a potential safety risk to those engaged in collecting or managing those used batteries.

An estimated 79 million medical devices operated with primary batteries were used in 2014. This figure, which does not include rechargeable batteries, represents 4.7% of all alkaline primary battery-operated devices, and the batteries used represent an estimated 5.7% of all alkaline primary batteries used. In raw numbers, this constitutes approximately:

- 310 million batteries, or
- 9,300 metric tonnes of batteries

With an expanding and aging population, and growth in the battery-powered medical device category, these numbers are expected to continue to grow and to make up a larger proportion of batteries used in the years to come. That means that batteries from medical devices will constitute a larger share of discarded batteries in the years to come.
The U.S. Food and Drug Administration’s (FDA) list of medical devices stretches to nearly 6,000 products. These products are categorized in three classes:

1. Class I devices, which are subject to the least regulatory control, present minimal potential for harm to the user, and are often simpler in design than Class II or Class III devices

2. Class II devices, which are subject to special controls, often including labeling requirements, mandatory performance standards, and post-market surveillance

3. Class III devices, which are subject to the most stringent controls because they often support or sustain human life, are importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury.

Examples of battery-containing devices in each category are:

- Class I devices: powered toothbrushes, otoscopes, lice removal kits, bed patient monitors, and certain hearing aids;
- Class II devices: glucose meters, pulse oximeters, powered wheelchairs, non-implanted electrical continence devices, and powered patient transfer devices; and
- Class III devices: automated external defibrillator system.

The differences between each class of medical devices are not relevant to the type or potential recyclability of batteries contained in them, and so should not govern the treatment of medical device batteries in a battery recycling bill.

For example, battery-powered surgery equipment is classified as Class I, the same as a powered toothbrush. Some items likely to be heavily used by seniors (and thus to increase in number based on the aging of baby boomers) – including glucose meters, pulse oximeters, powered wheelchairs, and powered environmental control systems – are Class II devices. An automated external defibrillator system is a Class III device.

Major concerns with the battery recycling legislation are as follows:

1. Contrary to some medical industry claims, subjecting medical devices to battery recycling legislation generally would not require medical device manufacturers to obtain additional clearance from the Food and Drug Administration (FDA).

Many simple devices (including certain types of hearing aids) are already exempt from any premarket review by the FDA. Of the devices that are subject to premarket clearance, the vast majority go through a “premarket notification” process known as a “510(k) submission.” Those relatively few non-exempt devices that are not eligible for the 510(k) process must be the subject of an application for Premarket Approval (PMA).
2. FDA’s guidance documents on changes to devices that are subject to 510(k) or PMA requirements make clear that simply changing from one brand of battery to another of the same type (e.g., 9 volt) would not require a new regulatory submission.

For example, for devices subject to the 510(k) requirements, following the decision-tree flowcharts leads to the conclusion that a change in the supplier of an equivalent battery does not require a new 510(k). Similarly, an FDA guidance document on changes to devices subject to the PMA requirements suggests a new clearance is needed to correct battery failures, but there is no indication that simply changing to a new supplier of the same type of initial battery would trigger any filing requirement. In any event, nothing in the proposed industry model bill is intended to affect vendor/supplier relationships. The model bill simply sets out a framework under which all battery manufacturers accept responsibility to manage batteries at end of life. Only if the manufacturer refuses to do so by failing to join a stewardship organization would the device manufacturer, distributor or retailer be required to assume financial responsibility for batteries in the medical device, but that should not create new FDA regulatory obligations for the device manufacturer.

It’s important to note that many rechargeable batteries are sold via distributors before they reach the equipment manufacturer who includes them with battery-containing products. Further, among rechargeable batteries, battery manufacturers generally sell components cells to other major companies that then make the cells into finished batteries without placing their brand names on the battery packs. Often, these intermediaries will not disclose the identities of the ultimate manufacturer using battery packs in products, which means that the battery manufacturer has little to no visibility into this area of the market. This illustrates the importance of ensuring that battery-recycling legislation reaches all makers of all products that come with batteries, subject to only limited exceptions.

The volume of battery-powered medical devices that use primary and/or rechargeable batteries is only going to continue to grow. CBR therefore believes that the responsible and fair approach to battery recycling legislation would exclude medical devices in only two situations:

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• Where the intended use of the device, regardless of FDA classification, is likely to result in it becoming contaminated with blood, urine, or other biological, chemical, or radiological hazards that would create risks for the persons collecting and managing the processing of spent batteries

• Where the batteries in the device are not intended to be removed and/or replaced except by the manufacturer.

Possible Hardship Exception:

When a medical device manufacturer can demonstrate that participation in a battery stewardship program would pose an undue hardship or disproportionately affect other regulatory compliance obligations applicable to specific medical devices, CBR would consider supporting a provision that allows a medical device manufacturer that meets hardship criteria to petition the state for relief from stewardship obligations for such devices to its model bill.
A sample list of
Battery-Powered Medical Devices

Several FDA regulations classifying certain medical devices specifically reference battery-powered devices. (Some classify devices that use battery power differently from those that use AC power.) Many other devices are battery-powered, although the relevant FDA regulatory specification does not specifically state that the devices may be battery-powered. While the list below is not exhaustive, battery-powered devices include those listed below in the following categories:

Anesthesiology Devices

1. Flexible laryngoscopes, 21 C.F.R. § 868.5530 (Class I)

Cardiovascular Devices

2. Indirect pacemaker generator function analyzer, 21 C.F.R. § 870.3640 (Class II).
3. Automated external defibrillator system, 21 C.F.R. § 870.5310 (Class III).
4. Pulse oximeters, 21 C.F.R. § 870.2700 (Class II)
5. Blood pressure monitors, 21 C.F.R. § 870.1130 (Class II)
6. External transcutaneous cardiac pacemaker (noninvasive), 21 C.F.R. § 870.5550 (Class II)
7. Ambulatory blood pressure monitors, 21 C.F.R. § 870.1130 (Class II)
8. Ambulatory electrocardiogram with arrhythmia detector and alarm, 21 C.F.R. § 870.1025 (Class II)
9. Vital signs monitoring patches, 21 C.F.R. § 870.2300 (Class II)
10. Electronic stethoscopes, 21 C.F.R. § 870.1875 (Class II)

Chemistry Devices

11. Glucose meters, 21 C.F.R. § 862.1345 (Class II)

Dental Devices

12. Pulp tester (dental device intended to measure pulpal vitality of teeth), 21 C.F.R. § 872.1720 (Class II)
13. Powered toothbrush, 21 C.F.R. § 872.6865 (Class I).

Ear, Nose, and Throat Devices

14. Audiometers, 21 C.F.R. § 874.1050 (Class II)
15. Gustometer (battery-powered device used for assessing the sense of taste), 21 C.F.R. § 874.1500 (Class I)
16. Hearing aid, 21 C.F.R. § 874.3300 (Class I or Class II) (batteries not specifically mentioned although nearly universally used)
17. Battery-powered artificial larynx, 21 C.F.R. § 874.3375 (Class I).
18. Otoscope, 21 C.F.R. § 874.4770 (Class I).

Gastroenterology Devices

20. Ingestible telemetric gastrointestinal capsule imaging system, 21 C.F.R. § 876.1300 (Class II).
21. Colon capsule endoscopy system, 21 C.F.R. § 876.1330 (Class II).
22. Pocket battery box or rechargeable battery accessory for endoscope, 21 C.F.R. § 876.1500 (Class II).
23. Urethral insert with pump for bladder drainage, 21 C.F.R. § 876.5140 (Class II).
24. Battery-powered transmitter outside the body for implanted electrical urinary continence device, 21 C.F.R. § 876.5270 (Class III).
25. Nonimplanted, peripheral electrical continence device connected by cable to a battery-powered pulse source, 21 C.F.R. § 876.5310 (Class II).
26. Nonimplanted electrical continence device (pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source), 21 C.F.R. § 876.5320 (Class II).

General and Plastic Surgery Devices

27. Battery-powered surgical instrument motors and accessories/attachments, 21 C.F.R. § 878.4820 (Class I).

General Hospital and Personal Use Devices

29. Battery-powered patient scale, 21 C.F.R. § 880.2720 (Class I).
31. Battery-powered medical examination light, 21 C.F.R. § 880.6350 (Class I).
32. Powered patient transfer device, 21 C.F.R. § 880.6775 (Class II).
33. Neonatal transport incubator, 21 C.F.R. § 880.5410 (Class II).
34. Lice removal kit, 21 C.F.R. § 880.5960 (Class I).
35. Electronic thermometers, 21 C.F.R. § 880.2190 (Class II)
36. Patient tracking wristbands, 21 CFR § 880.6310 (Class I)

Neurological Devices

37. Near Infrared (NIR) Brain Hematoma Detector, 21 C.F.R. § 882.1935 (Class II).
38. Biofeedback device, 21 C.F.R. § 882.5050 (Class II).

**Ophthalmic Devices**

39. Euthyscope, 21 C.F.R. § 886.1250 (battery-powered version is Class I) (a modified AC-powered or battery-powered ophthalmoscope (a perforated mirror device intended to inspect the interior of the eye)).
40. Keratoscope, 21 C.F.R. § 886.1350 (all versions exempt from premarket notifications, battery-powered version is exempt from GMP, no specific statement of Class).
41. Ophthalmoscope, 21 C.F.R. § 886.1570 (Class II).
42. Ophthalmic preamplifier, 21 C.F.R. § 886.1640 (Class II).
43. Retinoscope, 21 C.F.R. § 886.1870 (battery-powered version is Class II).
44. Tangent screen (campimeter), 21 C.F.R. § 886.1810 (Class I).
45. StereoScope, 21 C.F.R. § 886.1870 (Class I).
46. Spectacle dissociation test system, 21 C.F.R. § 886.1910 (Class I).
47. Transilluminator, 21 C.F.R. § 886.1945 (Class I for battery-powered device).
49. Radiofrequency electrosurgical cautery apparatus, 21 C.F.R. § 886.4100 (Class II).
50. Thermal cautery unit, 21 C.F.R. § 886.4115 (Class II).
51. Ophthalmic electrolysis unit, 21 C.F.R. § 886.4250 (Class I).
52. Operating headlamp, 21 C.F.R. § 886.4335 (battery-powered version is Class I).
54. Electronic vision aid, 21 C.F.R. § 886.5900 (Class I).
55. Image intensification vision aid, 21 C.F.R. § 886.5910 (Class I).
56. Optical vision aid, 21 C.F.R. § 886.5915 (Class I).

**Orthopedic Devices**

58. Goinometer, 21 C.F.R. § 888.1500 (Class I or Class II).

**Physical Medicine Devices**

59. Powered exoskeleton, 21 C.F.R. § 890.3480 (Class II).
60. Powered communication system, 21 C.F.R. § 890.3710 (Class II).
61. Powered environmental control system, 21 C.F.R. § 890.3725 (Class II).
   Powered wheelchair, 21 C.F.R. § 890.3860 (Class II).
63. Transdermal administration of medications (includes common drugs such as insulin), 21 C.F.R. § 890.5525 (Class III)