

Lithium Battery Regulations Nearly Short-Circuit Healthcare Shipment Monitoring

A company's letter to the Department of Transportation is just one response to the new restriction.

By Kevin O'Donnell

The U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration (DOT-PHMSA) last year amended the Hazardous



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Materials Regulations (HMR) expressly to tighten the safety standards for lithium battery transportation. These amendments, they state, "will enhance transportation safety by reducing fire hazards associated with lithium batteries and harmonize U.S. and international standards."

The final ruling, as it appears in the DOT Dangerous Goods Regulations (49 CFR Parts, 171, 172, 173, and 175, Hazardous Materials; Transportation of Lithium Batteries), became effective January 1, 2008. But like many Dangerous Goods Regulations, it is not without controversy, ambiguity, and interpretation, which has led at least one passenger airline to broadcast that they are no longer accepting cargo shipments containing devices powered by lithium batteries.



Henry Ames

compliant and/or meet the "special provisions" requirements for exceptions.

CRISIS AVERTED, FOR NOW

Direct negotiations with DOT on behalf of the healthcare industry, IATA Time and Temperature Task Force, and the data-logging industry at large, were led by Henry Ames, director of strategic marketing for Sensitech Inc. Sensitech, which has a vested interest in the outcome, submitted a formal request for interpretation of HMR 49 CFR Parts 171–180 to DOT. In a prompt written response from PHMSA director Edward Mazzullo, DOT said, "These cargo-monitoring devices are subject to applicable provisions of the HMR." Based on the extensive documentation Sensitech provided to

Such a knee-jerk reaction sent a leading temperature-monitoring company scrambling to request interpretation of the Final Rule from DOT, while proving that the batteries within their devices are

DOT relevant to its devices, however, he added "that these devices qualify for the exceptions provided for small lithium batteries under SP 188" (49 CFR 172.102).

Will other device manufacturers have to provide similar letters to DOT, to document the lithium content and configurations of their devices with the agency, and demonstrate conformity with the exception requirements? Perhaps. The HMR advises that "beginning October 1, 2009, the cells or battery must be of a type proven to meet the requirements of each test in the *UN Manual of Tests and Criteria 171.7*."

BUTTON-SIZED BATTERY

Lithium batteries are considered a hazardous material for purposes of transportation regulation because they can overheat and ignite under certain conditions and, once ignited, can be difficult to extinguish. They come in a near endless variety of shapes, sizes, and densities and are defined by two types: primary (nonrechargeable), which generally contain lithium metal, and secondary (rechargeable), containing an ionic form of lithium. In comparison with standard alkaline batteries, most lithium-ion (rechargeable) batteries

manufactured today contain an electrolyte and have a very high energy level susceptible to thermal runaway, a chain reaction leading to self-heating and release of its stored energy. DOT states that, “In general, the risks posed by lithium batteries are a function of battery size (the amount of lithium content and corresponding energy density) and the likelihood of short-circuiting or rupture.” In addition, “the quantity of lithium batteries in a shipment can also affect the severity of an incident.”

The PHMSA adds that like other products containing hazardous materials, lithium batteries can be transported safely, provided appropriate precautions are taken in design, packaging, handling, and emergency response. Special provisions within the document clearly indicate that certain types of lithium batteries may qualify for certain exemptions.

Every day, ironically, almost every passenger flight is accompanied by an endless assortment of lithium batteries. They power laptop and notebook computers, cameras, calculators, mobile phones, MP3 and personal DVD players, even onboard heart defibrillator machines and wristwatches. Passengers and crew alike carry and store them onboard or place them in checked luggage. It has become part of our flying routine, and we think nothing of it. In these instances of con-

sumer electronics and medical devices, DOT clearly has allowed for these exceptions (49 CFR Part 175.10).

What was not clear in the regulations, and what has caused a near “interpretation runaway” among some airlines, is whether or not devices containing lithium batteries attached to cargo were covered in the HMR. The

current Code of Federal Regulations as written primarily covers batteries as cargo—both bulk and within equipment itself—or batteries in carry-on or checked passenger luggage. It does not specifically address electronic data loggers within equipment, which some believe is left open to interpretation.

“The gray area in the current CFR created a serious potential threat to our healthcare system and overall patient safety,” says Ames. “On the one hand, one federal agency, the FDA, strongly suggests the use of monitoring equipment during transportation of drug product. On the other hand, another federal agency, the DOT, appears to be saying monitors are not allowed in cargo during transportation.”

This vague contradiction is what precipitated Delta Airlines Cargo Division to issue a statement to its customers on November 25, 2008, stating, “Effective immediately, Delta

Cargo cannot accept shipments containing devices powered by lithium batteries, regardless of the amount of lithium contained. Such devices include, but are not limited to temperature-sensitive shipments.”

The position taken by Delta was described by Jim Shimko, project manager in the corporate dangerous goods



Sensitech's TempTale monitors meet DOT's exception requirements for lithium batteries.

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group in the following manner: “There is nothing in the regulations that says you can ship these types of monitoring devices along with cargo—but there is nothing in the regulations that says you cannot either.” Hence, Delta has chosen a conservative interpretation of the regulations despite the fact that the devices are compliant with the limits outlined in CFR Part 172.102, section 188. A few other U.S. and international airlines have considered similar restrictions. Other global regulatory authorities could follow the DOT official response to this issue and allow special provisions for small lithium batteries contained in equipment.

EVER-PRESENT EXCEPTIONS

Nothing is ever clear-cut when it comes to Dangerous Goods Regulations. Invariably there are almost always exceptions, which DOT refers to as Special Provisions. 49 CFR Part 172.102 contains Special Provision 188, Small Lithium Cells and Batteries, which states: “Lithium cells or batteries, including cells and batteries packed with or contained in equipment, are not subject to any other requirements of this subchapter if they meet the following criteria:

Feature

Sensitech Inc. director of marketing Henry Ames says tens of millions of Sensitech's data loggers have been shipped aboard



• Packages that contain 5 kg or less net weight of primary lithium batteries or cells that are contained in or packed with equipment and the package contains no more than the number of lithium batteries or cells necessary to power the piece of equipment.

• For lithium metal or lithium alloy cell, the lithium content is not more than 1 g (2 g aggregate).

• For lithium-ion cell, the equivalent content is not more than 1.5 g (8 g aggregate).

• Effective October 1, 2009, the cells or battery must be of a type proven to meet the requirements of each test in the *UN Manual of Tests and Criteria* (171.7 of this subchapter).

• Cells or batteries are separated so as to prevent short circuits and are packed in a strong outer packaging or are contained in equipment.

Additional provisions are not relative to temperature-monitoring devices. Special Provision 188 addresses the "watch type" lithium batteries used to power nearly all temperature-monitoring devices. Their lithium content is roughly 0.062 g, well below the maximum allowable, and

they are included in the device in such a way as to be well protected and to prevent short circuits. The ambiguity seems to lie in whether a package's data logger device in the cargo hold of a passenger aircraft is a "piece of equipment," and whether the fact that it is activated is relevant.

"There have been tens of millions of our data loggers shipped aboard aircraft all over the world over the past couple of decades," Ames said. "While we have been requested to provide test data from airlines and other transportation service providers with regard to our devices, this is the first time, that I'm aware of, that an airline refused to ship them. Overall, I believe the risk to patient safety as a result of a product subjected to temperature abuse is significantly greater than the risk of any small lithium battery used in our devices which

we have demonstrated, and DOT agrees, are fully compliant with the current regulations."

ASSURING COMPLIANCE

Data logger manufacturers must pay particular attention to one aspect specific to the DOT requirements mentioned

TempTale monitors travel both to and from a destination, returning with a pre-made label.

above. Effective October 1, 2009, the cells or battery must be of a type proven to meet the requirements of each test in the *UN Manual of Tests and Criteria* (171.7 of this subchapter). These tests include, but are not limited to voltage discharge rates, and the robustness of the cells or batteries to withstand the rigors of transportation.

Additionally, Part 173.185 lists the general requirements for shipping and packaging, which include safety venting or package design which will preclude a violent rupture under conditions normal to transport, and must be equipped with an effective means to prevent reverse current flow and/or short-circuiting. This is where device manufacturers, whether they make data loggers, pumps, or other devices powered by small lithium batteries, need to perform their due diligence. It is the responsibility of each individual manufacturer to prove that the lithium batteries and cells used to power their devices are in compliance with the applicable parts of 49 CFR for content, configuration, application and testing, and meet the requirements of Special Provision 188. ■

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