

Pipeline and Hazardous Materials Safety Administration

April 15, 2024

Mr. Tristan Amberger 2007 Eastlake Ave E Apt 31 Seattle, WA 98168

Reference No. 23-0076

Dear Mr. Amberger:

This letter is in response to your August 18, 2023, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to lithium batteries.

We have paraphrased and answered your questions as follows:

- Q1. You ask what the definition of "production run" is for lithium batteries under the HMR.
- A1. The HMR does not define the term "production run" for lithium batteries. However, the word "production run" can be understood from the individual meaning of the words "production" and "run." The Merriam-Webster dictionary defines "production" as "the total output especially of a commodity or an industry" and "run" as "to continue in force, operation, or production." In the context of lithium batteries, a "production run" can be interpreted as the total quantity or batch of lithium batteries produced during a specific period of manufacturing operations.

It is important to note that § 173.22 of the HMR places the responsibility on the shipper to properly classify and package hazardous materials, including lithium batteries. While the term "production run" is not explicitly defined, the HMR provides specific requirements for the packaging and testing of lithium batteries based on their lithium content and other characteristics, which may be relevant in determining what constitutes a "production run" for compliance purposes.

- Q2. You ask whether a change in the design of a lithium battery or a change in the lithium battery production process constitutes a new production run.
- A2. The answer depends on the specific changes to the design of the lithium battery or the lithium battery production process. The determination of criteria that triggers a new production run is ultimately up to the manufacturer. However, in general, changes to a cell or battery design or production process equivalent to those found in section 38.3.2.2 of the UN Manual of Tests and Criteria could indicate a new production run.
- Q3. You ask whether the replacement of a lithium battery cooling fan with a newer model cooling fan would constitute a new production run.

- A3. See answer A2. This determination is the responsibility of the manufacturer.
- Q4. You ask whether transitioning from a sealing process that relies on a technician physically sealing a lithium battery component to a process that utilizes a validated automated procedure with a robotic dispenser is considered a new production run.
- A4. See answer A2. This determination is the responsibility of the manufacturer.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

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Steven W. Andrews Jr.

Acting Chief, Regulatory Review and Reinvention Branch

Standards and Rulemaking Division

Sent: Monday, August 14, 2023 6:28 PM

To: INFOCNTR (PHMSA)

<INFOCNTR.INFOCNTR@dot.gov> Subject: Request for

LOI

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Dear Sir or Madam,

I was hoping to get a letter of interpretation regarding the definition of a "production run" as it is stated in 49 CFR 173.185(e)

I found LOI 17-0071, which clearly stipulates that the quantity defined as a low production run is no more than 100 units. With that stated and understood, what defines the "production run" itself?

Based off of freely available information, I could define a production run as "all of the processes necessary to manufacture a certain product" (Harper Collins online)

Does a change in the design of the battery itself or a change to the production process constitute a new production run?

Battery design example:

Due to a quality issue, Manufacturer XYZ updated the design of Battery XYZ 1.0 to replace a model of cooling fan for a newer cooling fan that of higher quality. Does that design change constitute a new production run?

Production process example:

Manufacturer XYZ has produced 85 units of a battery with a sealing process that involved a technician to seal a component of the battery by hand. After validation of an automated procedure using a robotic dispenser, they update the production process to use the robot instead of the technician. Does the change to the production process count as a new production run?

If any of these conditions COULD constitute a new production run, what steps would the manufacturer have to take to define a new production run of a battery?

Thanks,

Tristan Amberge