

1200 New Jersey Avenue, SE Washington, DC 20590

Pipeline and Hazardous Materials Safety Administration

October 2, 2024

Ben Smith Sr. Multimodal DG Specialist ProteQ 2325 Dulles Corner Blvd Ste 725 Herndon, VA 20171

Reference No. 24-0070

Dear Mr. Smith:

This letter is in response to your July 24, 2024, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the requirements for prototype lithium cells or batteries found in 49 CFR 173.185(e).

We have paraphrased and answered your questions as follows:

- Q1. You ask whether the meaning for "low production" and "prototype" lithium cells or batteries in § 173.185(e) are intended to be the same.
- A1. The answer is no. While the exceptions in § 173.185(e) can apply to both low production runs of lithium cells or batteries and to prototype lithium cells or batteries transported for purposes of testing, these two terms are separate.
- Q2. You ask whether there is a maximum quantity of prototype lithium cells or batteries transported for purposes of testing that are permitted to be offered by air annually.
- A2. The answer is no. However, to qualify for the exceptions in § 173.185(e) the prototype lithium cells or batteries must be transported for purposes of testing.
- Q3. You ask whether § 173.185(e) limits low production lithium cells or batteries to 100 (or less) offered in commerce for air transportation per year.
- A3. Section 173.185(e) defines a low production run of batteries as "annual production runs consisting of not more than 100 lithium cells or batteries." This is a production limit, not a limit on annual shipments by air or other mode. If more than 100 of a lithium cell or battery type are produced in an annual production run, those lithium cells or batteries are not considered a low production run.

- Q4. You ask whether there is a limit on the number of prototype lithium cells or batteries transported for purposes of testing that a shipper can offer into commerce annually.
- A4. The answer is no. If the prototype lithium cells or batteries are being transported for purposes of testing, there is no annual limit on the number of prototype lithium cells or batteries a shipper can offer into commerce annually. However, any prototype lithium cells or batteries being transported for purposes other than testing would not qualify for the exceptions in § 173.185(e). Please note that PHMSA cannot determine whether the lithium cells or batteries in your specific scenarios are prototypes being transported for purposes of testing based on the information provided.
- Q5. If the answer to question Q4 is yes, you ask whether a manufacturer is limited by each design type they produce or by all UN 38.3 untested prototypes lithium cells or batteries across all design types they produce.
- A5. See answer A4. There is no annual shipment limit for prototype lithium cells or batteries as long as they are being transported for the purposes of testing. Please note that PHMSA cannot determine whether the lithium cells or batteries in your specific scenarios are prototypes being transported for purposes of testing based on the information provided.

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

Sincerely,

alexan Wallato

Alexander Wolcott Acting Chief, Regulatory Review and Reinvention Branch Standards and Rulemaking Division

Jacobson

24-0070

| From: | INFOCNTR (PHMSA) |
|--------------|--|
| To: | Dodd, Alice (PHMSA) |
| Cc: | Hazmat Interps |
| Subject: | FW: Request for Written Letter of Intrepretation |
| Date: | Tuesday, August 6, 2024 2:22:25 PM |
| Attachments: | Request for Written Letter of Intrepretation.msq |
| | |

Hello Alice,

See the attached interpretation request. Let us know if you need anything else.

Best, Aminah

-----Original Message-----From: Ben Smith <bsmith@proteq.com> Sent: Wednesday, July 24, 2024 10:18 AM To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov> Subject: Request for Written Letter of Intrepretation

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To Whom it may Concern :

Our client (the grantee of a PHMSA CAA), manufactures lithium metal batteries in the U.S., that are then shipped to their EU facility, and installed in implantable medical devices for further evaluation and developmental testing including FDA approval testing. Our client offers these *prototype* batteries into commerce for air transport as UN 3090 under the regulatory authority of ICAO SP A88 and 49 CFR§ 173.185(e) for shipping prototype batteries.

49 CFR § 173.185(e) use the terms "low production runs," and "prototype" in describing the applicability of the standard. The regulatory language of § 173.185 (e) seems to limit "low production runs" to no more than 100 cells or batteries per year, and then separates by a comma (in the language of the regulations) "prototype" lithium cells or batteries. Our questions are:

- 1. Is PHMSA's definition of "low production," and "prototype" batteries intended to be one in the same?
- 2. If the "low production," and "prototype" are meant to be different, what is the maximum quantity of "prototype" batteries that are permitted to be offered into commerce via the air mode annually?
- 3. Both SP A88, § 173.185(e) and the CAA appear to suggest that a shipper (manufacturer) of low production batteries is limited to permitting 100 or less batteries offered into commerce for air transport per year. Is this correct?
- 4. If there is a limit of the number of protype batteries offered into commerce annually, and our client manufacturer's several UN38.3 untested design type batteries (different models and sizes of prototype UN3090), does the limitation of the number of batteries per year apply to each design type of UN38.3 untested prototype batteries (again different models), or does the annual limitation apply to all UN38.3 untested prototype batteries manufactured at our clients facility?

Thank you and we look forward to your reply.

Ben Smith



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