StandardAero Business Aviation Services, LLC.

Rechargeable Lithium Battery Installations

In lieu of § 25.1353(b)(1) through (4) at amendment 25–123, or § 25.1353(c)(1) through (4) at earlier amendments, each rechargeable lithium battery installation must:

1. Be designed to maintain safe cell temperatures and pressures under all foreseeable operating conditions to prevent fire and explosion.
2. Be designed to prevent the occurrence of self-sustaining, uncontrollable increases in temperature or pressure, and automatically control the charge rate of each cell to protect against adverse operating conditions, such as cell imbalance, back charging, overcharging and overheating.
3. Not emit explosive or toxic gases, either in normal operation or as a result of its failure that may accumulate in hazardous quantities within the airplane.
4. Meet the requirements of § 25.863.
5. Not damage surrounding structure or adjacent systems, equipment, or electrical wiring from corrosive fluids or gases that may escape in such a way as to cause a major or more-severe failure condition.
6. Have provisions to prevent any hazardous effect on airplane structure or systems caused by the maximum amount of heat it can generate due to any failure of it or its individual cells.
7. Have a failure sensing and warning system to alert the flight crew if its failure affects safe operation of the airplane.
8. Have a monitoring and warning feature that alerts the flightcrew when its charge state falls below acceptable levels if its function is required for safe operation of the airplane.
9. Have a means to automatically disconnect from its charging source in the event of an over-temperature condition, cell failure or battery failure.

Note: A battery system consists of the battery, battery charger and any protective, monitoring and alerting circuitry or hardware inside or outside of the battery. It also includes vents (where necessary) and packaging. For the purpose of this special condition, a battery and battery system are referred to as a battery.

Issued in Kansas City, Missouri, on July 20, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–15837 Filed 7–22–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2017–D–6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.'' This guidance updates the previous version of the guidance, ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking,'' issued July 1, 2020. This final guidance explains FDA's compliance policy regarding Global Unique Device Identification Database (GUDID) submission requirements for certain class I devices considered consumer health products and describes how a labeler of a class I devices can determine if its device is one of these devices. Additionally, the guidance explains that FDA intends to extend our existing compliance policy regarding GUDID submission requirements for class I and unclassified devices, other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices, for an additional 75 calendar days.

DATES: The announcement of the guidance is published in the **Federal Register** on July 25, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6841 for ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Indira Konduri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1104, Silver Spring, MD 20993–0002, 301–796–6658 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.'' On September 24, 2013 (78 FR 58786), FDA published a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use (the UDI Rule). Phased implementation of the regulatory requirements set forth in that final rule is based on a series of established compliance dates based primarily on device classification.

The UDI Rule requires a device to bear a unique device identifier (UDI) on its label and packages unless an exception or alternative applies (21 CFR 801.20), and special labeling requirements apply to stand-alone software regulated as a device (21 CFR 801.50). The UDI Rule also requires that data pertaining to the key characteristics of each device required to bear a UDI be submitted to FDA's GUDID (§ 830.300 (21 CFR 830.300)). In addition, the UDI Rule added 21 CFR 801.18, which requires certain dates on device labels to be in a standard format. For devices that: (1) must bear UDIs on their labels and (2) are intended to be used more than once and reprocessed between uses, 21 CFR 801.45 requires the devices to be directly marked with a UDI. Compliance dates for these labeling, GUDID submission, standard date format, and direct marking requirements can be found in the preamble to the UDI Rule (78 FR 58815–58816). For more information about UDI compliance dates, please see the UDI web page, available at: *https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/compliance-dates-udi-requirements.*

This final guidance supersedes the guidance: ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking, Immediately In Effect Guidance for Industry and Food and Drug Administration Staff'' (''2020 UDI Compliance Policy Guidance''), issued July 1, 2020 (85 FR 39477). This guidance explains FDA's compliance policy regarding GUDID submission requirements under § 830.300 for certain class I devices considered consumer health products and describes how a labeler of a class I device can determine whether its device is within the scope of that policy. With respect to class I devices that are consumer health products, as described in the guidance, FDA believes that the entry of UDI data into GUDID, especially given the frequent changes to the Universal Product Codes (UPCs) serving as the UDIs for these devices, is burdensome to stakeholders. Further, FDA considered the public health benefit of GUDID submission for consumer health products and the risks to public health if GUDID submission is not provided for these devices. After reviewing available postmarket information, such as medical device reports and recall data for class I devices, FDA has a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product lifecycle, as well as those for which GUDID information may be less important in this regard. Based on this analysis, at this time, FDA does not intend to enforce the GUDID submission requirements under § 830.300 for consumer health products. We are implementing this change in policy through guidance to allow FDA and stakeholders an opportunity to fully assess its impact on public health. FDA may consider amending its regulations on this subject in the future.

In addition, the final guidance explains that we intend to extend our existing compliance policy regarding GUDID submission requirements for class I and unclassified devices, other than I/LS/LS devices, regardless of whether they are consumer health products, for an additional 75 calendar days. In the 2020 UDI Compliance Policy Guidance, FDA stated that we did not intend to enforce the GUDID submission requirements under § 830.300 for class I and unclassified devices, other than I/LS/LS devices, before September 24, 2022. At this time, in light of the considerations described in the guidance, FDA does not intend to enforce the GUDID submission requirements under § 830.300 for class I and unclassified devices, other than I/LS/LS devices, before December 8, 2022.

This guidance finalizes the draft guidance entitled ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Requirements for Certain Devices.'' A notice of availability of the draft guidance appeared in the **Federal Register** of October 14, 2021 (86 FR 57154). FDA considered comments received and revised the guidance as

appropriate in response to the comments, including further clarifying which devices are considered consumer health products.

The portion of this guidance describing the 75-day extension of FDA's existing compliance policy regarding GUDID submission requirements for class I and unclassified devices, other than I/LS/LS devices, is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that this is a less burdensome policy that is consistent with public health. Although this policy is being implemented immediately without prior comment, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17029 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
801, subpart B, and 830	Unique Device Identification	0910–0720
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15828 Filed 7–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 559

RIN 3141–AA76

Facility License Notifications

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) is amending its facility license notification regulations to remove the requirement that a facility license notice submission include the name and address of the proposed gaming facility. Specifically, the National Indian Gaming Commission changes to require the submission of the name and address of the property *only if* known when the facility license notification is submitted to the NIGC Chair. The Commission proposes this action to assist tribal governments, and tribal gaming regulatory authorities that face challenges in meeting the regulatory requirement where a facility has not yet been issued a name or address.

DATES: This rule is effective August 24, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, National Indian Gaming Commission; Telephone: (202) 632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission (NIGC or Commission) and sets out a comprehensive framework for the regulation of gaming on Indian lands. On February 1, 2008, the NIGC published a final rule in the **Federal Register** titled ''Facility License Notifications and Submissions'' (73 FR 6019). The rule amended the then-current facility license regulations to provide for an expedited review to confirm a tribe's submittal of facility license information; to require notice to the NIGC when a tribe issues, renews, or terminates a facility license; to streamline the submittal of certain information relating to the construction, maintenance, and operation of a gaming facility; and to provide that a tribe need not submit a notification of seasonal or temporary closures of less than 180 days.

II. Development of the Proposed Rule

On June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the Facility License notifications and submission requirements. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendments to the regulations were intended to implement flexibilities for tribes that submit notification of a new facility and