

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.

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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

that facility has not yet been assigned a physical address at the time of submission.

The Commission held two virtual consultation sessions in July 2021 to receive tribal input on the possible changes. The Commission reviewed all comments and now proposes these changes which it believes will allow Tribes greater flexibility in submitting facility license notifications and afford the Agency greater efficiency in processing the applications.

III. Review of Public Comments

In response to our notice of proposed rulemaking, published December 1, 2021, 86 FR 68200, the NIGC received two comments.

General Comments

Comment: One commenter supports the proposed rule because the Tribal government may not know the gaming facility name or address when a facility license notice (FLN) is submitted to the Chair. Since the proposed revision contemplates this possibility, the commenter believes the proposed rule reduces a burden on tribal governments, and increases efficiency, which they believe will prove beneficial.

Another commenter supports the proposed rule because they don't believe the name and address of a property is necessary to determine whether the location of a gaming facility is Indian lands. The commenter believes the change eliminates needless red tape because Tribal governments would no longer be required to unnecessarily wait for such information to be available before submitting a FLN. Finally, the commenter believes the change will improve efficiency.

Response: The NIGC agrees with both commenters and will amend its regulations accordingly.

IV. Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of \$100 million or more. The rule will not cause a major increase in costs or prices for consumers,

individual industries, Federal, State, local government agencies or geographic regions. Nor will the rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501, *et seq.*, and assigned OMB Control Number 3141–0012.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC consultation policy specifies that it will consult with tribes on Commission Actions with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian

tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes.

Pursuant to this policy, 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 notification process.

List of Subjects in 25 CFR Part 559

Gambling, Indian—lands, Indian—tribal government, Reporting and recordkeeping requirements.

Therefore, for reasons stated in the preamble, 25 CFR part 559 is amended as follows:

PART 559—FACILITY LICENSE NOTIFICATIONS AND SUBMISSIONS

■ 1. The authority citation for part 559 continues to read as follows:

Authority: 25 U.S.C. 2701, 2702(3), 2703(4), 2705, 2706(b)(10), 2710, 2719.

■ 2. Amend § 559.2 by revising paragraph (b) to read as follows:

§ 559.2 When must a tribe notify the Chair that it is considering issuing a new facility license?

* * * * *

(b) The notice shall contain the following:

(1) A legal description of the property;

(2) The tract number for the property as assigned by the Bureau of Indian Affairs, Land Title and Records Offices, if any;

(3) If not maintained by the Bureau of Indian Affairs, Department of the Interior, a copy of the trust or other deed(s) to the property or an explanation as to why such documentation does not exist; and

(4) If not maintained by the Bureau of Indian Affairs, Department of the Interior, documentation of property ownership.

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Dated: July 13, 2022, Washington, DC.

E. Sequoyah Simermeyer,
Chairman.

Jeannie Hovland,
Vice Chair.

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