

Contains Nonbinding Recommendations

Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency

Guidance for Industry

April 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1304 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to FDAThirdpartyprogram@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1304 and complete title of the guidance in the request.

Questions

For questions about this document, contact FDA at FDAThirdpartyprogram@fda.hhs.gov.

Table of Contents

| | | |
|------|-------------------|---|
| I. | Introduction..... | 1 |
| II. | Background..... | 2 |
| III. | Discussion..... | 4 |

Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

The Accredited Third-Party Certification Program regulation (21 CFR part 1, subpart M) establishes a voluntary program for the recognition of accreditation bodies (ABs) that accredit third-party certification bodies (CBs) to conduct food safety audits and issue food or facility certifications to eligible foreign entities for the purposes specified in sections 801(q) and 806 of the FD&C Act (21 U.S.C. 381 and 384b).¹ The regulation requires that recognized ABs and accredited CBs perform certain onsite observations and examinations.

¹ For information on Part 1, Subpart M, see <https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program> and <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-accredited-third-party-certification>.

Contains Nonbinding Recommendations

Due to the impact of the public health emergency related to COVID-19, FDA is issuing this guidance to provide the Accredited Third-Party Certification Program's currently-recognized ABs and accredited CBs flexibility, in certain circumstances, regarding the following requirements:

- The requirement for recognized ABs to monitor the performance of CBs they have accredited under the program by conducting onsite observations of a representative sample of regulatory audits performed by the CBs they accredited and to visit the CBs' headquarters (or other location, as needed) no later than 1 year after the initial date of accreditation of the CB and every 2 years thereafter.
- The requirement that certificates be issued for a term only up to 12 months for already-issued certifications issued under the Accredited Third-Party Certification Program.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services Act (42 U.S.C. 247(d)(a)(2)).

Given this public health emergency, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Coronavirus

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³

² Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

Contains Nonbinding Recommendations

Governments across the globe have instituted travel restrictions and advisories in an effort to curb the spread of COVID-19. As a result of the travel restrictions and advisories implemented to address the public health emergency related to COVID-19, FDA expects that the recognized ABs and accredited CBs currently participating in the Accredited Third-Party Certification Program may have difficulties meeting the requirements to conduct onsite observations and examinations. FDA is issuing this guidance to address some of these concerns and provide flexibility in certain circumstances during the public health emergency related to COVID-19.

B. Requirements for Recognized ABs Monitoring Accredited CBs

After accrediting a CB, recognized ABs must monitor the performance of the CB(s) they accredited (21 CFR 1.621). The monitoring requirements include activities that can be conducted remotely (21 CFR 1.621(a)), and also activities that must be conducted onsite (21 CFR 1.621(b)). The monitoring activities that recognized ABs may conduct remotely are an annual comprehensive assessment of the performance of each CB they accredited by reviewing the CB's self-assessments, the regulatory audit reports and notifications submitted to FDA under 21 CFR 1.656, and any other information reasonably available to the recognized AB regarding the compliance history of eligible entities that the accredited CB certified or that is otherwise relevant to determining whether the accredited CB is in compliance with the regulation (21 CFR 1.621(a)).

The monitoring activities that recognized ABs must conduct onsite are observations of a representative sample of regulatory audits performed by the accredited CB (or its audit agents) and a visit to the accredited CB's headquarters (or other location that manages audit agents under this program), no later than one year after the initial date of accreditation of the CB and every 2 years thereafter for the duration of the CB's accreditation (21 CFR 1.621(b)).

C. Requirement that Certificates be for a Term of Up to 12 Months

The basis for the issuance of certifications under the Accredited Third-Party Certification Program is that an accredited CB must complete a regulatory audit that meets the requirements of 21 CFR 1.651 and any other activities that may be necessary to determine an eligible entity's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations (21 CFR 1.653(a)(1)). The regulatory audit must include, among other activities, an unannounced onsite examination (21 CFR 1.651(c)(1)-(2)). The regulatory audit must be sufficiently rigorous to allow the accredited CB to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under the Accredited Third-Party Certification Program (21 CFR 1.651(c)(3)).

The certificates may only be for a term of up to 12 months (see 21 CFR 1.653(b)(1); section 808(d) of the FD&C Act). When the certification for an eligible entity expires, the accredited CB must conduct a new regulatory audit (including an unannounced onsite examination) in order to issue a new certification (21 CFR 1.653(a)).

Contains Nonbinding Recommendations

After issuing a certificate, if an accredited CB has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited CB must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited CB must immediately notify FDA, under 21 CFR 1.656(d), if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. *See* 21 CFR 1.654.

Section 808(c)(2)(B) of the FD&C Act specifies two uses for the certifications issued by accredited CBs under this program: for participation in the Voluntary Qualified Importer Program (VQIP) under section 806 of the FD&C Act and for import certification under section 801(q) of the FD&C Act.

III. Discussion

To help address the difficulties with conducting onsite observations and examinations, we are providing temporary flexibility so that ABs can maintain the accreditations of CBs and so that already-issued certifications need not lapse.

FDA does not intend to enforce certain onsite observation and certificate term requirements in the following circumstances:

For recognized ABs monitoring their accredited CBs, FDA does not intend to enforce the requirements in 21 CFR 1.621(b) that, within 1 year after the initial date of accreditation and every 2 years thereafter, the recognized AB conduct onsite observations of a representative sample of regulatory audits performed by the accredited CB (or its audit agents) and that the recognized AB visit the CB's headquarters (or other location that manages audit agents conducting food safety audits under the regulation), when:

- A recognized AB determines that it is impracticable to conduct onsite observations of regulatory audits or visit an accredited CB's headquarters (or other location) due to government travel restrictions or advisories related to COVID-19; and
- The recognized AB conducts the annual comprehensive assessment of the performance of a CB it has accredited in accordance with 21 CFR 1.621(a) to determine whether the accredited CB is in compliance with the regulation.⁴

Recognized ABs should resume onsite observations and visits within a reasonable period of time after it becomes practicable to do so.

For already-issued certificates, FDA does not intend to enforce the requirement that the accredited CBs issue the certificates for a term only up to 12 months (21 CFR 1.653(b)(1)), when:

⁴ This policy only applies when a recognized AB has already accredited CBs under the Accredited Third-Party Certification Program regulation. The policy does not apply to the evaluations that an AB conducts for CBs that are *seeking* accreditation or for accredited CBs *seeking* scope expansion.

Contains Nonbinding Recommendations

- The accredited CB determines that it is impracticable to conduct a regulatory audit due to government travel restrictions or advisories related to COVID-19;
- The regulatory audit would ordinarily be needed to support the issuance of a new certificate under 21 CFR 1.653(a)(1);
- The accredited CB has already issued a food or facility certificates to the eligible entity under 21 CFR 1.653 that is due to expire;⁵
- The food or facility certificate has not been suspended or withdrawn by the accredited CB; and
- The accredited CB continues to adhere to the requirements of 21 CFR 1.654 regarding monitoring eligible entities to which they have issued certificates.

An accredited CB that has issued a certificate with an upcoming expiration date can contact FDA at FDAtirdpartyprogram@fda.hhs.gov to discuss the term of the current certificates. Accredited CBs should resume conducting regulatory audits to determine if the eligible entities should be issued new certificates within a reasonable period after it becomes practicable to conduct the onsite examinations required for regulatory audits.

⁵ This policy only applies to already-issued certificates under the Accredited Third-Party Certification Program.