

Letter to Industry Announcing the Launch of the CDRH Export Certification and Tracking System (CECATS)

U.S. Food & Drug Administration

Nov. 29, 2012

Dear Medical Device Establishments:

Today the FDA's Center for Devices and Radiological Health (CDRH) launched the first phase of a new, Internet-based system for submitting and processing export document requests. The CDRH Export Certification and Tracking System (CECATS) will allow industry to submit export document requests electronically as a voluntary alternative to paper submissions.

During the first phase, CECATS will be available only for Certificates to Foreign Governments, which account for 95 percent of all export certificate requests submitted to CDRH.

In 2013, CDRH expects to implement the second phase for the following requests:

- Certificates of Exportability
- Non-Clinical Research Use Only Certificates
- Simple Notifications of Medical Device Exports
- Export Permit Letters

CECATS automates many of the steps that exporters and CDRH perform when submitting and processing export document requests. The advantages to exporters include:

- Reduction in certificate processing time;
- Real-time validation that eliminates the need to return submissions;
- Elimination of the cost of mailing the request; and,
- Real-time status updates available via the Internet.

Please see our list of [frequently asked questions](#) [1] (FAQs) for detailed instructions on accessing this new system. In addition to the FAQs, online training sessions on CECATS will be held via [Adobe Connect](#) [2] at 2 to 3:30 p.m. (EST) on Monday, Dec. 3, 2012, Tuesday, Jan. 8, 2013, and Tuesday, Feb. 5, 2013. We encourage participants to [test their connection](#) [3] prior to the webinar. Please note that while you do not need to pre-register for these sessions, participants will not be able to enter the meeting until the host has logged in on the day of the event.

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CDRH looks forward to continuing to improve the processing of all export document requests, with a goal of providing the best service possible. If you have any questions concerning CECATS, please send an email to CDRHCECATS@fda.hhs.gov [4] or call (301) 796-7400 (press option #3 for export-related inquiries).

Sincerely yours,

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Links:

- [1] <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm329896.htm>
- [2] <https://collaboration.fda.gov/cecats/>
- [3] https://collaboration.fda.gov/common/help/en/support/meeting_test.htm
- [4] <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/mailto:CDRHCECATS@fda.hhs.gov>