

Risk Based Device Inspections

The FDA Reauthorization Act of 2017, FDARA, changed the basis for scheduling device inspection. Prior to enactment, device establishments were subject to inspection once in every two-year period following the establishment's registration. The change, in Section 701 of FDARA, moves from a calendar based system to a risk-based system.

The change brings the device inspection into alignment with the previous drug based inspection schedule. The text of the section, 21 USC §360(h), is available from <http://uscode.house.gov/view.xhtml?req=%28%28title%3A%2821%29+AND+section%3A%28360%29%29%29&f=treesort&fq=true&num=0&hl=true&edition=prelim&granuleId=USC-prelim-title21-section360>

The law requires the FDA to establish a risk-based schedule for inspecting devices establishments. The schedule depends on two major factors:

- Consideration of whether the company participates in certain international device audit programs
- Risk based factors as described below

The law identifies six factors that influence the schedule:

- The company's compliance history
- Recalls linked to the company
- The inherent risk of the device
- The inspection frequency and history of the company
- Whether the company has had an inspection by a foreign government
- Any other criteria necessary and appropriate

To date, FDA has not provided information of the implementation details.