



# Recent Changes to MDSAP

Date: 2018/05/09

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# New MDSAP Transition Guidance

Notice  
April 4, 2018

In light of stakeholders  
feedback

Health Canada announced  
modifications to the  
transition process

## Enforcement discretion for audits in 2018

Manufacturers to submit a valid MDSAP certificate by  
December 31st, 2018

- Health Canada will not take enforcement action against manufacturers that can demonstrate that they have undergone an audit
- We are sensitive to the challenges of both scheduling the audit and issuing the certificate

# New MDSAP Transition Guidance

Notice  
April 4, 2018

In light of stakeholders feedback

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## Transition to MDSAP through surveillance audits

### Manufacturers must meet the following conditions:

- initial or re-registration audit after 2016/01/01
- certificate under CMDCAS valid until 2018/12/31
- Maintain a valid ISO 13485 certificate as of 2019/01/01

### Manufacturers must provide the following:

- Certificate under CMDCAS valid until 2018/12/31
- Valid ISO 13485 certificate issued after 2016/01/01
- MDSAP Surveillance Audit Confirmation Notification

OR

evidence of arrangements to undergo MDSAP audit

Will allow manufacturers to maintain their existing certification cycle

# Audit Duration Adjustment

Notice

April 27, 2018

In light of stakeholders feedback

Health Canada & MDSAP Consortium announced revised procedure for audit duration calculations

## Audit duration adjustments for SMEs

### **New procedure in effect - June 11, 2018**

- AOs responsible to make the adjustments on a case-by-case basis as applicable

### **To be eligible, a manufacturer must:**

- Have 100 or fewer employees
- Make lower-risk products (typically class II)
- Use only simple design and manufacturing processes using commonly available materials
- Have a good history of compliance to 13485

The adjustments are on a sliding scale and range from 5% to 42%