



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

REGULATORY CONTROL OVER RAPID CHANGE OF MEDICAL SOFTWARE & HEALTH IT INDUSTRY



DITTA
GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT &
RADIATION THERAPY
TRADE ASSOCIATION





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

XXX SOFTWARE

Version 1.0 – Initial Release

Version 1.0 A – Bug Fix

Version 1.1~1.5 – Minor New Feature added

Version 2.0 – Major Change:

Change of Intended Use





SCENARIO 1: FREQUENT CHANGE OR UPDATES OF SOFTWARE



Scenario

- Software version release is very fast and License amendment process cannot catch the speed of the release. Customer cannot use latest version of software (which might be a safer & advanced version);
- Multiple version of changes pending before the license amendment is completed.
- In some jurisdiction they may not continue to deliver version 1.0 due to safety issues, if it links to safety alerts

Consequence

- Latest version such as 1.2>2.0 cannot be supplied until Ver. 1.0A &/or 1.1 is/are approved. Manufacturer must submit another license amendment for later version, total time to gain market access cannot be estimated/ predicted



SCENARIO 2: LONG DEVELOPMENT TIMELINE FOR SOFTWARE FIX TOGETHER WITH NEW FEATURE



Scenario

- A. In some jurisdictions, manufacturer may not be able to continue supply version 1.0 & 1.1, due to safety issues for 1.0 and 1.1 were not reviewed by authority. Authority demands manufacturer should update their license before new delivery continues.
- B. Software that has higher Medical Device risk classification or software safety classification, the development, verification and validation process could be longer - up to 1-1.5 year.

Consequence

1. No new delivery until FSCA/recall is closed. However, adding up the time required for license amendment the whole process could take more than 1.5 - 2 year.
2. New customer cannot purchase the product even though user notice is supplied, user understands the risk, manufacturer / local distributor guarantee the upgrade when it is released.
3. New customer complains and patients have no access this product
4. A long queue of patients in order to use this medical system, patients suffer from waiting and delayed medication / treatment.



DITTA

GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

THANK YOU!

