Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Guidance for Minor Change Reporting

Authoring Group: Work Group 1, Pre-Market: General MD

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1 Purpose

The purpose of this document is to streamline the procedures for reporting and handling minor changes of an approved medical device by allowing manufacturers and relevant industries to report minor changes upon occurrence (occasional report) or alternatively report an overview of changes once a year (annual report). When an occasional report is made on a minor change, there is no need to repeat it in the annual report. The purpose is to reduce additional administrative paper work.

Medical device manufactures are obligated to establish appropriate change control process and risk management. There is due diligence to ensure any changes to a medical device are carefully and adequately assessed, followed up and documented in the QMS.

2 Definitions

- **Minor Change:** Any modification that does not affect safety or performance of a medical device which obtained a marketing authorization

- **Annual Report:** A comprehensive report on minor changes throughout the preceding year. An applicant can submit an annual report (once per year) autonomously within the designated period.

- **Occasional Report:** A report on minor changes upon occurrence. Unlike an annual report, an occasional report is submitted upon occurrence of minor changes.

- **Applicants:** Manufacturers or Authorized Representative of medical device

3 Submission and Handling Procedures

3.1 Applicants

Reports on any minor changes of an approved (or declared/certified) medical device that obtained a marketing authorization are recommended to be submitted as follows.

3.1.1 An applicant shall fill out the information correctly on the Minor Change Report Form (Appendix 1) and submit the form to the regulatory authority electronically or through other means as appropriate.

3.1.2 If such report is submitted electronically, the applicant may use a specific electronic system of the regulatory authority.

3.1.3 If there are high frequencies for minor changes and an applicant wants to report the changes through an annual report, an applicant shall submit the Minor Change Report Form (Appendix 1) immediately within the designated period calculated based on the initial approval date. The period should be a twelve-month period, counting forward from the month of the initial approval date. The annual report should be submitted within the first month of the calculated period.

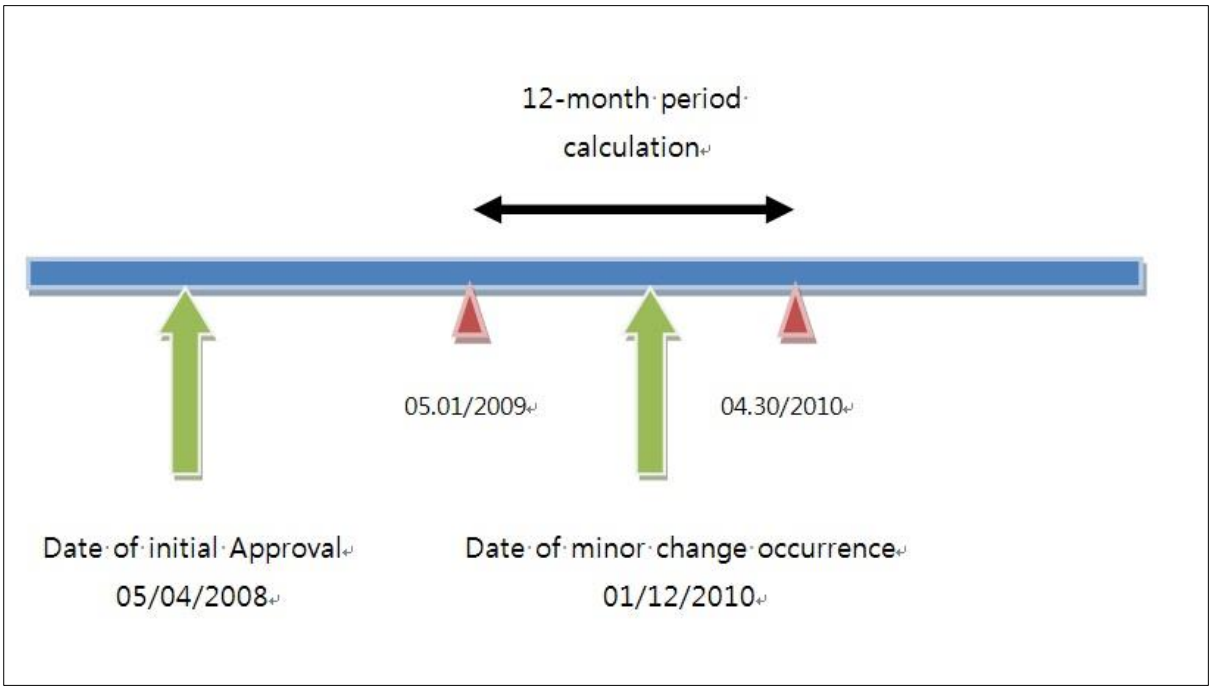
Example: If the approval date is May 4, 2008 and the minor changes occur on January 12, 2010, the designated period should be as follows.

Table 1 - Example of period calculation for an annual report

Date of Initial Approval	Date of minor change occurrence	12-month period calculation for an annual report	Submission Period
05/04/2008 (MM/DD/YYYY)	No minor change occurrence	05/04/2008 – 04/30/2009	Not Applicable
	01/12/2010 (MM/DD/YYYY)	05/01/2009 – 04/30/2010	05/01/2010 – 05/31/2010*

Note:
* The period for annual report should be a 12-month period, counting forward from the month of the initial approval date. The annual report should be submitted within the next month from the calculated period.

Figure 1 - Example of period calculation for an annual report



3.1.4 An applicant shall submit the Minor Change Report Form (Appendix 1) and record a description for minor changes, the date of occurrence, and a consequence/outcome of the changes should be added to the Minor Change Report Form to be attached to the existing medical devices license (or declaration/certification).

Table 2 - Example of Occasional Reporting

Date	Information to be recorded on license/declaration/certification
01/12/2010 (MM/DD/YYYY)	1. Color of the external case: From Blue to Red

Table 3 - Example of Annual Reporting

Date	Information to be recorded on license/declaration/certification	Application/Receipt Date
01/12/2010 (MM/DD/YYYY)	1. Color of the external case: From Blue to Red	05/10/2010 (MM/DD/YYYY)
02/15/2010 (MM/DD/YYYY)	2. Packaging unit: 1 Box (from 10 ea. to 5 ea.)	

3.1.5 E. A minor change must be recorded both in the Minor Change Report Form to be attached to of the medical device license and in the Quality Management System (QMS) upon occurrence as well as in other quality management documents if necessary.

3.2 Regulatory Authority

The regulatory authority regularly monitors minor changes reported by a medical device manufacturer.

If a significant change is reported as a minor change, the regulatory authority should notify the applicant of the fact and take the necessary regulatory action

4 Examples of the Types of Minor Changes

The list provided below is for indication only and is not exhaustive.

Figure 2 - Examples of the Types of Minor Changes

Category 1. No change in a medical device itself

1. A change in the manufacturer address without a physical move due to an administrative change in the address
2. A change in the location of a manufacturer supplier who requests manufacture due to a change of an administrative district

Category 2. A change in the medical device name

3. Deletion of a medical device name due to suspension of production or due to a marketing decisions to stop selling the model
4. Addition of a medical device name due to a change in the color of external appearance of a non-invasive medical device, without changing its intended use and function
5. Change in Trademark

Category 3. Change of raw materials of a medical device

6. A change in the assigned name or the number of component in an electric medical device
7. Change of the version due to correction of a defect (bug) from the existing content of the medical device license (or declaration/certification) without adding a new function of medical device software, if not affecting performance and safety of the device
8. Change of the version due to correction of a defect (bug) from the existing content of the medical device license (or declaration/certification) without adding a new function of medical device software, if not affecting performance and safety of the device

Category 4. Change of components in a medical device

9. Deletion or change of a non-critical component, or changes in component, subsystem or accessory which is not a medical device when used alone, if not affecting performance and safety of the device

Category 5. Change of external appearance of a medical device

10. Change of color. Not applicable if the medical device is in contact with blood, body fluid or drug inserted or injected into the human body, or if medicine is added to the medical device.
11. Change in the shape or location of a handle, button, etc. which does not affect the mechanical and electrical safety of the device

Category 6. Change of packaging or container of a medical device

Note: Packaging refers to plastic wrapping/bags or cardboard box/cases for external protection of medical devices. It may include the labeling or not, depending on the packaging types.

12. Change of packaging design. Not applicable if the packaging is sterilized
13. Change of a container not in direct contact with a medical device. Not impacting the integrity of the device during shipping/transportation.

5 Appendix 1: Minor Change Report Form

<table>
<tr><td colspan="4">Minor Change Report
for a Medical Device</td><td>□ Annual
□ Occasional</td></tr>
<tr><td rowspan="2">Applicant</td><td>① Name</td><td colspan="2"></td><td></td></tr>
<tr><td>③ Address</td><td colspan="3">(Name and Phone No. of Person in Charge)</td></tr>
<tr><td rowspan="2">Manufacturer (distributors/ Importers)</td><td>④ Company Name</td><td colspan="2"></td><td>⑤ Company Phone No.</td></tr>
<tr><td>⑥Company Address</td><td colspan="3"></td></tr>
<tr><td colspan="2">⑦ Types of Business</td><td colspan="3">□ Manufacturing □ Import □ Distributor</td></tr>
<tr><td colspan="2">⑧ Business License No.</td><td></td><td>⑨Approval No.</td><td></td></tr>
<tr><td colspan="2">⑩ Product Name
Item Name
Device Model Name</td><td></td><td>⑪ Class
Classification Code
.</td><td></td></tr>
<tr><td colspan="5">Minor Changes to be reported</td></tr>
<tr><td>⑩ Medical Device</td><td>⑪ Previously Approved Element/Component</td><td>⑫ Changes</td><td colspan="2">⑬ Date and Reason for changes</td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="5">I hereby submit a minor change report in accordance with the applicable laws and regulations.

MM DD YYYY

Applicant (Signature and Official Stamp*)

*as applicable</td></tr>
</table>