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|  | Policy Title: Naming Convention of MDSAP Electronic Records | Document No.: MDSAP QMS P0015.003 |
| | | Version Date: 2017-08-23 |

Table of Contents

| | |
|--|---|
| 1. Purpose | 1 |
| 2. Scope | 1 |
| 3. Definition/Acronyms | 1 |
| 4. Authorities/Responsibilities | 1 |
| 5. Procedures | 2 |
| 5.1 Format - General Concept..... | 2 |
| 5.2 Format - Specifics | 2 |
| Appendix 1- Codes assigned to each AO..... | 5 |

1. Purpose

The purpose of this document is to define a coherent, unequivocal and systematic way of naming MDSAP records.

2. Scope

The naming convention specified in this procedure applies to the name of the electronic file in MDSAP record repository(ies).

This document is not to specify any record format or reference to the Auditing Organizations (AOs). For example, each AO may have their unique certificate identification system, generating certificate numbers of diverse formats.

3. Definitions/Acronyms

DUNS - A proprietary system developed and regulated by Dun & Bradstreet (D&B) that assigns a unique numeric identifier, referred to as a "DUNS number" to a single business entity.

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|---|--------------------------------------|-------------|
| Naming Convention of MDSAP Electronic Record | Document No.: MDSAP QMS P0015.003 | Page 2 of 5 |
|---|--------------------------------------|-------------|

4. Authorities/Responsibilities

The assignment of the record identifier is under the responsibility of the following functions/entities:

- For the assessment documents: the Assessment Program Manager (APM)
- For the audit documents: the MDSAP Secretariat upon receipt of the record
- For the internal QMS records: the MDSAP QMS Management Representative.

5. Procedures

5.1 Format – General Concept

The principle of the naming convention is based on the assembly of concise and meaningful information in a specified order.

Each document will be named using the format **YYYY-MM-DD-AAA-(issuing AO identifier)-(Entity Identifier)-(NN)-(ANN).VVV**, where:

- YYYY-MM-DD is the most meaningful record date (refer to table below)
- A 3-letter code corresponding to the type of record (AAA)
- If applicable, the identifier of the AO issuing the record (AOID)
- If applicable, the identifier of the assessed or audited entity to which the record pertains (AOID for the assessed AO, or DUNS for the audited manufacturer)
- A numerical chronological order (NN)
 - (If two NCs are initiated the same day, then the date will not be sufficient to differentiate between the two. An additional key is necessary to differentiate the different records. Example: the first would be listed as NN=01, the second as NN=02 and so forth)
- A version number (VVV) (Example: 001=first version; 002=second version)

To distinguish between the identifier of the AO and of the manufacturer without ambiguity and make the reference more “user-friendly”, the manufacturer is identified by its DUNS number and the AO is identified by a 4-letter code based on the name of the AO. See Appendix 1 for codes assigned to each Auditing Organization recognized by Health Canada as of Jan.1, 2014 under the CMDCAS program.

Attachments to a record have the same name than the record it relates to, with an extension under the format **–ANN** and its specific version number. For example, the attachment #1 to report 2014-09-18-ASR-BSIA.001 could be 2014-09-18-ASR-BSIA-A01.003.

5.2 Format – Specifics

The table below lists the MDSAP records and their specific identifier format.

| Records | Identifier Format | Date |
|---|--|--|
| Assessment Records | | |
| Application | YYYY-MM-DD- APP -AOID.VVV | Receipt of the application |
| Notice of Change | YYYY-MM-DD- NOC -AOID.VVV | Receipt of the notice |
| Assessment Program Management File | YYYY-MM-DD- APM -AOID.VVV | Approval of the APM |
| Monitoring Report | YYYY-MM-DD- MON -AOID.VVV | Issue of the report |
| Assessment Plan | YYYY-MM-DD- ASP -AOID.VVV | 1 st day of the assessment |
| Assessment Report | YYYY-MM-DD- ASR -AOID(-Type).VVV ¹ | 1 st day of the assessment |
| On Site Attendance | YYYY-MM-DD- OSA -AOID(-Type).VVV | 1 st day of the assessment |
| Witnessed Audit - Manufacturer Profile Form | YYYY-MM-DD- MAN -AOID-DUNS.VVV | Receipt of the profile form |
| Witnessed Audit – Audit Plan | YYYY-MM-DD- AUP -AOID-DUNS.VVV | 1 st day of the witnessed audit |
| Witnessed Audit Report | YYYY-MM-DD- WIT -AOID-DUNS.VVV | 1 st day of the witnessed audit |
| AO Nonconformity Report | YYYY-MM-DD- ANC -AOID-NN.VVV | Issue of the NC |
| Technical Review | YYYY-MM-DD- TER -AOID.VVV | Review by the APM |
| Technical Review and Decision File | YYYY-MM-DD- RAD -AOID.VVV | Committee meeting |
| Authorization Letter | YYYY-MM-DD- AUT -AOID.VVV | Issue of the letter |
| Recognition Letter | YYYY-MM-DD- REC -AOID.VVV | Issue of the letter |
| AO Planning of Audit | YYYY-MM-DD- PLA -AOID.VVV | Receipt of the planning |
| Audit records | | |
| Nonconformity Grading and Exchange Form | YYYY-MM-DD- NGE -AOID-DUNS.VVV | Receipt of the document |
| Audit Reports | YYYY-MM-DD- AUR -AOID-DUNS.VVV | 1 st day of the audit |
| Manufacturer Nonconformity Reports | YYYY-MM-DD- MNC -AOID-DUNS-NN.VVV | Issue of the NC |
| Certification Document (i.e. certificate) | YYYY-MM-DD- CER -AOID-DUNS-NN.VVV | Issue of the certificate |
| Internal QMS Documents | | |
| Internal Audit Report | YYYY-MM-DD- IAU -RA ² .VVV | 1 st day of the audit |
| Concern Resolution Report | YYYY-MM-DD- CRR -NN.VVV | Initiation of the CRR |
| MDSAP Management Review | YYYY-MM-DD- MMR .VVV | Review meeting |

¹ Assessment Report file name may be completed with an additional suffix for the assessment type (ST1 for Stage 1, ST2 for Stage 2, SU1 for Surveillance #1, RER for Re-recognition, SPR for Special Remote, SPO for Special On-Site)

² Internal Audit Report file name may be completed with the country of the Regulatory Authority audited (AUS for Australia, BRA for Brazil, CAN for Canada, JAP for Japan and USA for United States)

6. Forms

- MDSAP QMS F0015.1.002 SFTP File Structure for AS and AU Records
- MDSAP QMS F0015.2.001 Checklist of Information to Provide by the Assessment ATL to the APM

7. Document History

| Version No. | Version Date | Description of Change | Author Name/Project Manager |
|-------------|--------------|--|-----------------------------------|
| 001 | 2014-02-10 | Initial Release | Marc-Henri Winter |
| 002 | 2015-06-09 | <p>Following types of records were included in the naming conventions:</p> <ul style="list-style-type: none"> - Consolidation of several record types (RA nonconformity report, complaint and feedback, corrective action, and preventive action) into a single Concern Resolution Report (YYYY-MM-DD-CRR-NN.VVV) - See more detail on this consolidation with the creation of the Concern Resolution Procedure, superseding the Feedback and complaint, nonconformity, corrective and preventive action procedures) - Update of appendix: correction of AOs' information (name for BSI, Intertek, DUNS for Intertek and UL) | Marc-Henri Winter |
| 003 | 2017-08-23 | <ul style="list-style-type: none"> - Added the FDA MDSAP email address instead of the MDSAP Secretariat to the footer. - Updated version date and number - Updated Appendix 1 in the following ways: Added NSF Health Science Certification; Removed LGA Intercert GmbH; Changed "SAI Global Certifications Ply Ltd.'s" name to "QMI-SAI Canada Limited." - Re-formatted in accordance with MDSAP QMS F0002.2 - Removed naming convention for RA Nonconformity Reports, Complaints and Feedback, Corrective Action, Preventive Action, which will be named as Concern Resolution Reports - Removed Assessment Team Recommendation naming convention - Included Technical Review, Authorization Letter and On Site Attendance naming convention - Changed the naming convention for Internal Audits | Andrew Durfor / Patricia Serpa |

Version 003
Approval

Approved: Signature on File Date: August 23, 2017
MDSAP Lead Project Manager for RAC Chair

Appendix 1:

Auditing Organizations' AOID Code

| Auditing Organization | AOID Code |
|---|-----------|
| BSI Group America, Inc. | BSIA |
| DEKRA Certification B.V. | DEKR |
| DQS Medizinprodukte GmbH | DQSM |
| Intertek Testing Services NA, Inc. (ITS) | ITSN |
| Laboratoire national de métrologie et d'essais, Division certification G-MED (LNE/G-MED) | GMED |
| Lloyd's Register Quality Assurance Inc. (LRQA) | LRQA |
| National Standards Authority of Ireland (NSAI) | NSAI |
| NSF Health Sciences Certification | NSFC |
| QMI-SAI Canada Limited | SAIG |
| SGS United Kingdom Ltd. | SGSU |
| TUV Rheinland of North America, Inc. | TUVR |
| TÜV SÜD America Inc. | TUVS |
| TUV USA, Inc. | TUVU |
| UL LLC | ULAB |