	Policy Title:	Document No.:
MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM	MDSAP Medical Device Regulatory Audit Reports	MDSAP AU P0019.004
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FOREWORD

This document describes the format and content of Medical Device Single Audit Program (MDSAP) medical device regulatory audit reports submitted to regulatory authorities participating in the Medical Device Single Audit Program. Participating MDSAP Regulators have included elements to assist those authorities in effectively using the audit reports in accordance with their legislation.

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1. Introduction

1.1 Policy Objective

This document describes the expectations of the regulatory authorities participating in the Medical Device Single Audit Program (MDSAP) in relation to the content of medical device regulatory audit reports prepared by recognized auditing organizations. The objective is to reduce variations in the outcome of the application of regulatory

audit procedures with respect to medical device manufacturers and recognition procedures with respect to auditing organizations.

The content of medical device regulatory audit reports must satisfy requirements for: third-party Quality Management System (QMS) audit reporting for Conformity Assessment (Australia); supporting an application for, or maintenance of a device registration request (Brazil); the manufacturer Good Manufacturing Practice (GMP) conformity evaluation (Brazil); a medical device license (Canada); QMS Inspection Guideline (Japan), or, a third-party audit for the United States.

1.2 Policy Statements

Medical device regulatory audit reports and certificates issued by MDSAP-recognized auditing organizations in support of the Medical Device Single Audit Program will comply with this procedure. Auditing organizations are to ensure that medical device regulatory audits and audit reports satisfy the requirements set out in *IMDRF/MDSAP WG/N3 (2nd Edition) - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition* and *IMDRF/MDSAP WG/N4 - Competency and Training Requirements for Auditing Organizations*, as well as other applicable MDSAP procedural and guidance documents.

1.3 Scope and Application

The scope of this guidance document is limited to the information that participating MDSAP Regulatory Authorities require in medical device regulatory audit reports for all audits, other than stage 1, the information necessary for participating MDSAP regulatory authorities to effectively use the audit reports in accordance with their legislation, the format of reports, and a discussion in relation to acceptable practices.

Special Audits are extraordinary audits in that they are not part of the planned audit cycle. Auditing Organizations should only use Special Audits when necessary and should focus on specific elements of the manufacturer's QMS and/or other country specific regulatory requirements. The report generated from a Special Audit should record in detail the applicable elements audited and the state of conformity to regulatory requirements. Reports from Special Audits will be recorded using the fillable MDSAP Audit Report Template as described in section 2.1 of this document, but may be limited to the applicable sections listed in 2.3.2 and 2.3.3 that were audited during the Special Audit.

This document applies to all MDSAP-recognized auditing organizations.

1.4 Background

Whereas a certificate is an attestation of conformity to requirements, the corresponding audit report represents a significant portion of the objective evidence of the implementation of a conformity assessment procedure. The audit report serves as a written record of the audit team's determination of the extent of fulfillment of specified requirements. It also serves to demonstrate the application of the rules of the recognized Auditing Organization's conformity assessment scheme.

The participating Regulatory Authorities will use different work products from MDSAP. For example, to comply with the applicable subsections of sections 32, 34 and 43.1 of the Canadian Medical Device Regulations, a manufacturer must provide a valid QMS certificate to Health Canada. A valid certificate, as issued by a Health Canada recognized Auditing Organization, is an attestation on the part of the auditing organization that the QMS of the manufacturer has been audited against ISO 13485:2016 in accordance with Health Canada's requirements and has been found to be in conformity for the scope of activities as outlined on the certificate. Other Regulatory Authorities will use an audit report prepared in accordance with these guidelines as evidence to satisfy regulatory requirements.

1.5 Definitions

Auditing Organization (AO)

An organization that audits a medical device manufacturer for conformity with quality management system requirements. Auditing organizations may be independent organizations or a Regulatory Authority which performs regulatory audits. (IMDRF/MDSAP WG/N3 (2nd Edition))

Manufacturer

Any natural or legal person[1] with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

[1] The term "person" that appears here includes legal entities such as a corporation, a partnership or an association.

Notes:

1. This ‘natural or legal person’ has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
2. The manufacturer’s responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
3. ‘Design and/or manufacture’, as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
4. Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.
5. Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
6. An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.
7. To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

Organization

Group of people and facilities with an arrangement of responsibilities, authorities and relationships

Example: Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.

Note 1: The arrangement is generally orderly.
Note 2: An organization can be public or private.
Note 3: This definition is valid for the purposes of quality management system

standards. The term “organization” is defined differently in ISO/IEC Guide 2. (ISO 9000:2015)

The term “organization” in the context of this document refers to the entity that was audited. An organization may be a “manufacturer”.

In addition to the definitions above, the definitions found in the following documents apply:

- ISO 9000:2015 Quality management systems - Fundamentals and vocabulary
- ISO/IEC 17000:2005 - Conformity assessment - Vocabulary and general principles

2.0 Guidance for Implementation

2.1 Report Format

The report must be generated using the fillable MDSAP Audit Report Template.

2.2 Report Language

The language of the report is subject to the operating language of the auditing organization and should be understandable by the manufacturer; however, all audit reports must also be available in English.

It is preferable that report authors prepare reports using the grammatical form of “active voice” using first person (with the identification of the first person when there are multiple authors) and the past tense. Active voice ensures that the focus of a sentence is on the correct subject, reducing ambiguity and improving clarity. First person ensures the specific individual responsible for an audit activity or audit finding can be identified.

2.3 Report Content

2.3.1 Information about the Organization

The audit report should contain information that unambiguously identifies the name of the organization, the physical location of the audit, the standard applied by the organization for the quality management system, and the medical devices that are part of the scope of the audit. The following items should be included in the report:

a) Organization’s Name and Address

The report should include the name and address of the organization subject to the audit, as it would appear on a registration certificate.

b) Organization Identification Number

The organization's identification numbers assigned by each of the participating regulatory authorities for the site audited should be included in the audit report. Where a manufacturer does not market in a jurisdiction, or has no licensed devices in the case of Health Canada, a manufacturer identification number will not exist. In such cases, a notation of 'N/A' or 'not applicable' should be made.

When an audit is made of an organization that is not the manufacturer, the audit report must clearly reference the manufacturer and the relationship of the audited organization to the manufacturer.

When a multisite audit is necessary to maintain a manufacturer's scope of certification/MDSAP suitability, a report of each audited organization will be generated. The report of each audited organization will clearly reference the manufacturer and the relationship of the audited organization to the manufacturer. For multisite audits, the report of the manufacturer will clearly identify all organizations audited to support a certification/MDSAP suitability decision and describe their relationship to the manufacturer. This will allow all reports generated to support a certification/MDSAP suitability decision to be easily assembled. The audit of separate buildings within the same physical campus is not considered a multisite audit.

c) Corporate Identity of the Organization

The report should record a correct reference for the organization when there are multiple names or identities. This clarification also extends to any relationships with other separate entities, including subsidiaries, acquisitions, business units, and joint ventures. When preparing this section, auditors should comprehensively explain the relationship between the organization's entities in the context of their QMS, and the associated scope of manufacturing activities and devices.

This item may be omitted from surveillance audit reports if there have been no changes since the last audit.

d) Date of the last audit

The report must include the date of the last audit of the organization. If this is the initial audit of the organization, this must be stated in the report.

e) Description of the audited organization

A description of the audited organization should be included in the report. This description should include the approximate number of employees and associated number of shifts. The description should also include an overview of the activities and processes carried out by the audited organization at the audited location as well as identification of key outsourced activities. The name and title of senior management of the site audited should be included in the description. Senior management includes the most responsible individual for the site being audited as well as those responsible for establishing, implementing, and maintaining the quality management system.

The report should identify all locations when manufacturing activities involve more than one physical site and include a description of the relationships between the sites and their relative roles, including any shared functions.

For surveillance audit reports the description of the audited organization may be limited to those parts that fall within the scope of the audit.

f) Scope of Certification

The report should include the scope of certification of the manufacturer, if applicable. This includes activities and a list of the generic medical device groups or families that are included in the scope of certification. The report may refer to an appendix when the scope of certification is extensive.

Note: If the manufacturer exports products to Brazil and/or Japan, the report must include a list with the name of the medical devices with their respective risk class and registration number. This list may be part of the report or be referred to in an appendix.

g) Identification of Critical Suppliers

The report should identify the legal name, full address, and product or service of critical suppliers that provide products or services used in the audited processes. The involvement of a supplier may be through an outsourced process such as sterilization, software development, or design and development activities. Where the list is prohibitively long, the report may refer to an appendix.

h) Contact Person

The name and contact information of the organization’s point of contact should be included in the report.

i) Jurisdictions

The report should include the list of jurisdictions taken into account for the audit, i.e. jurisdictions to which the organization claims regulatory compliance.

j) Exclusions and Non-Applications of MDSAP Requirements

The report should identify when the audited organization has claimed an exclusion or non-application of a MDSAP requirement, or has claimed an exclusion from the requirements of jurisdictions where the manufacturer does not intend to market their devices.

2.3.2 Information about the Audit

The audit report should describe in adequate detail the nature of the audit performed and the following items:

a) Audit Type

The report should identify the type of audit performed (for example, initial audit [a.k.a. initial certification audit], surveillance, re-audit [a.k.a. re-certification audit], etc.) In the context of the MDSAP, an extraordinary audit conducted to follow-up a significant nonconformity identified during a normally scheduled audit is considered a Special Audit.

b) Audit Criteria

The report should list the audit criteria. For audits performed per the MDSAP, this would normally include, as a minimum, the applicable regulatory requirements for the participating regulatory authorities.

c) Audit Objectives

The report should list the audit objectives. These should refer to, as applicable according to IMDRF/MDSAP WG/N3 (2nd Edition) clauses 9.3.3, 9.6.2 and 9.6.5, the evaluation of:

- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;
- product/process related technologies;
- adequate product technical documentation in relation to relevant regulatory requirements; and,
- the manufacturer's continued fulfillment of these requirements.

Note: The depth of the review of product technical documentation will be dependent on the medical device risk classification. This audit reporting criterion excludes:

- the premarket reviews typically performed by product specialist(s); and,
- the final decisions of safety and performance of a medical device made by any Regulatory Authority)

d) Audit Scope

The report should include the scope of the audit. In particular, the report should identify the physical locations and organizational units of the audit and, in the case of a surveillance audit, the activities and processes that form the scope of the audit.

e) Audit Dates

The dates of the on-site audit should be included in the audit report.

f) Identification of the Audit Team

The report should identify all members of the audit team (name, title, affiliation) and describe their respective role (e.g. team leader, technical expert, etc.), the identity of any interpreter and their affiliation, and the identity of any observers present.

g) Audit Language

The report should indicate the language or languages used during the audit.

h) Stage 1 Audit Results

Reports of initial audits should include the results of the Stage 1 audit (e.g. documented findings, audit report, etc.). When elements of Stage 1 and Stage 2 audits are combined during a single on-site audit of the manufacturer, the report should include a statement that all Stage 1 and Stage 2 requirements were audited.

i) Audit Plan

The report should include a copy of the audit plan. The report should document and explain any deviations from the audit plan. The audit plan may be attached to the report.

2.3.3 Audit Findings

The audit report should include sufficient audit findings, both positive and negative, to support the audit conclusions made in the report. The auditor should explain the context of an audit finding, support the finding with objective evidence and evaluate the finding against the appropriate audit criteria.

Any nonconformity regarding a requirement of a participating regulatory authority, including but not limited to, nonconformities regarding device marketing authorization and adverse event and advisory notice reporting, must be recorded as a nonconformity in the audit report.

During the course of an audit, the audit team may independently identify a requirement that was not fulfilled and that has already been identified and recorded as a nonconformity (NC) by the manufacturer. In this case, the auditors shall record a separate NC for the requirement that was not fulfilled, **unless** the following criteria are met:

- the NC was documented and investigated according to the manufacturer's QMS;
- the remediation action plan, including corrections and corrective actions, as appropriate, had been defined and authorized, and had been or are being implemented, according to a specified timeframe;
- the specified timeline for implementing the planned remediation actions is respected and consistent with the significance of the nonconformity and the nature of the planned remediation actions;
- the manufacturer has a process to assess the effectiveness of the remediation actions implemented; and,
- all corresponding requirements of ISO/IEC13485:2016 Clause 8.5.2 and 8.5.3 relating to corrective and preventive action, and, any additional requirements of a participating regulatory authority relating to corrective and preventive action, are being fulfilled.

A NC against the corrective and preventive actions requirements should be considered in cases of previously identified issues that have not been properly addressed. Use MDSAP AU F0019.2 NC Grading and Exchange Form. The diagram in appendix 1 presents the relevant process flow.

Whenever a NC is independently identified by the audit team, the auditors should use the requirements of GHTF/SG3/N19:2012 to determine the NC grade, and to verify if the actual criticality of the NC was properly assigned by the manufacturer. In this evaluation, the auditor shall not consider NCs that have been previously identified by the manufacturer as a repeat NC.

If a NC was classified as grade 4 or 5, the auditor shall note the information in *MDSAP AU F0019.2 NC Grading and Exchange Form* and use the specific field on column AE to clearly identify that this NC was previously identified, recorded and is being appropriated handled by the manufacturer. In this case, the auditor shall also include a

brief description in *Section 11 – Audit Findings* to document that all above criteria are fulfilled.

The information that the auditor shall record in Section 11 includes:

- an identifier for the NC report and, if applicable, the CAPA report;
- the date that the NC and CAPA were opened;
- a description of, and timeframes for, the corrective and preventive actions defined by the manufacturer;
- a statement of whether nonconforming, or potentially nonconforming, medical devices, have been released to the field.

NOTE 1: Particular attention should be paid to situations where nonconforming or potentially nonconforming devices have been released by the manufacturer due to a nonconformity with the requirements for design or manufacturing, or where the device may not be able to maintain a state of conformity throughout its labeled lifetime due to latent design or manufacturing nonconformities (GHTF/SG3/N19:2012 - Grade 4 or 5 NCs).

An Auditing Organization is to report to the recognizing Regulatory Authorities within 5 working days; when the NC is a Grade 5 NC, when there are more than two Grade 4 NCs, or when they become aware of a public health threat, fraudulent activity or counterfeit products (IMDRF/MDSAP WG/N3 (2nd Edition) – clauses 8.6.2, 8.6.4 and 9.5.3 and MDSAP AU P0027).

Regulatory Authorities will not treat NCs that were previously identified, recorded and are being appropriately handled by the manufacturer at the time of the audit as NCs that should be reported to a Regulatory Authority within a 5 day time frame.

When the audit team identifies a nonconformity that is under remediation, was previously identified and appropriately recorded by the manufacturer, fulfills all the requirements mentioned above, and is classified as grade 1, 2 or 3, it is not necessary to document the NC using the *MDSAP AU F0019.2 NC Grading and Exchange Form*. In these cases, the audit team may exercise their discretion as to whether to record a brief description about the audit finding in *Section 11 – Audit Findings and/or in* Section 16 – *Conclusions,* in the field *"Recommendation on Follow-up Actions".*

The Auditing Organizations may need to verify the complete implementation, or the effectiveness of remedial action, prior to the next routine audit, if they consider it necessary, or upon request by the recognizing Regulatory Authority(s). Alternatively, the complete implementation, or the effectiveness of the remediation action, shall be verified during the next routine audit. The auditors shall record their verification in *Section 14 – Follow-up of the past nonconformities* of the report.

If it is verified that the NC is still present at the following audit, then the auditor must issue a NC and grade it in accordance with N19. At this point, the auditors shall consider the finding as a repeated NC.

In cases where the remediation plan, including corrections or corrective actions associated with the nonconformity were not implemented as proposed, then the auditor must also issue a NC against the requirements for corrective and preventive action.

The participating MDSAP Regulatory Authorities will conclude that an Auditing Organization that omitted an aspect of the audit, or a process of the organization's QMS, did not audit that aspect or process. If a process of the organization's QMS that is required to be audited by the audit type (e.g. initial, surveillance, re-audit) is not audited, the report should contain the rationale for not auditing the process.

The report should record both Findings and Observations as important components of a complete and accurate record of the audit. Report authors should refrain from providing specific advice, instructions or solutions towards the development and implementation of a QMS, or from suggesting opportunities for improvement. Observations may include situations where the collection of audit evidence was insufficient to support a finding of nonconformity.

a) Audit Summaries

Written summaries of the audit of each applicable MDSAP process or activity audited should be included in the report. The audit summaries should be brief but nonetheless include the following information:

i) description of the QMS process or activity audited;
ii) description of the area (physical or organizational) of the site visited;
iii) name and title of persons interviewed;
iv) key documents reviewed (procedures, work instructions, etc.);
v) type and number of documents (documents or records) reviewed, including a qualitative statement of the sample size where appropriate;
vi) identification of the products or components relevant to the process or activity audited; and,
vii) concluding statements regarding whether the activity or process under audit is in conformity with the audit criteria.

Note: the inclusion of clause numbers in the concluding statements can assist with demonstrating appropriate coverage.

The audit report must also include the following MDSAP process specific information in an audit summary as applicable (e.g. as applicable to the type of organization audited and/or audit conducted). The report should document the review of the process, and record how a state of conformity or nonconformity was determined.

- Management:

i) the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verification of the proper documentation of controls in the quality management system;

ii) verification that management reviews are being conducted at planned intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements;

iii) description of the organization's organizational structure and verification as to whether or not the responsibilities and authorities (e.g., management representative) were established;

iv) description of the organization's documents and records control; and

v) verification that the organization has determined the competencies for personnel performing work affecting product quality, including a description of the training procedures and records verified.

- Device Marketing Authorization and Facility Registration:

i) determination as to whether or not the organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP.

- Measurement, Analysis and Improvement:

i) determination as to whether or not appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, and data from the monitoring of products, processes, nonconforming products, and suppliers;

ii) confirmation that data from these sources are accurate and analyzed using valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action;

iii) description of the quality data sources chosen for review during the audit;

iv) determination as to whether or not investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible; and confirmation that investigations are commensurate with the risk of the nonconformity;

v) confirmation that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices; and verification that corrective action and preventive action is appropriate to the risk of the nonconformities or potential nonconformities encountered;

vi) verification that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements and to determine the effectiveness of the quality system;

vii) confirmation that the internal audits include provisions for auditor independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions; and

viii) confirmation that the organization has made effective arrangements for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process; and verification that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.

- <u>Medical Device Adverse Events and Advisory Notices Reporting:</u>

i) determination as to whether or not the organization's processes ensure that individual device-related adverse events and advisory notices involving medical devices are reported to regulatory authorities within required timeframes; and

ii) a listing of the advisory notices applicable to each of the regulatory authorities participating in the MDSAP. The listing should include whether the advisory notice was reported to the regulatory authority in the jurisdiction where the device is marketed.

- <u>Design and Development:</u>

i) a brief description of the design and development project(s) selected for review, and the rationale for the selection of the project(s);

ii) description of the records reviewed for the selected design and development project;

iii) verification that risk management activities are defined and implemented for product and process design and development, risk acceptability criteria are established and met throughout the design and development process, and any residual risk is evaluated and, where appropriate, communicated to the customer;

iv) determination that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s);

v) verification that the results of validation includes the presence and completeness of clinical evidence

vi) verification that product and production specifications are fully documented prior to design release or design changes for transfer to production. In particular, where applicable, that:

a. production parameters derived from process validation / revalidation are reliably transferred to routine production activities, e.g. for a viral inactivation process; for the uniformity of content for medicine/device combinations; for sterilization, requirements for bioburden monitoring, environmental monitoring and controls, dose audits, etc.

b. for devices containing tissues, cells or substances of animal or microbial origin requirements for breeding/culturing, veterinary checks, sacrificing/harvesting, segregation, transport, storage, testing and handling of material to be incorporated into a device (e.g. ISO 22442 for animal origin) are followed.

vii) for devices containing medicinal substances, requirements for storage, sampling and identification testing of starting materials in accordance with a recognized pharmacopeia (BP, EP, JP, USP) and a Medicinal Code of GMP, for testing of finished devices against a validated test method or recognized pharmacopeia (BP, EP, JP, USP), where applicable, and requirements for maintaining stability are followed.

viii) determination that control of design and development changes, including changes to manufacturing processes affecting the characteristics of the medical devices, are subject to design and development verification and validation, as applicable, addressing the new or impacted risks;

ix) for products where design controls are a permitted exclusion, verification that the organization has available and is maintaining adequate technical documentation to demonstrate conformity to safety and performance requirements and other relevant regulatory requirements.

- Production and Service Controls:

i) brief description of the manufacturing, incoming inspection and warehouse areas and production process(es);

ii) description of the controls for receiving, handling, storage and distribution of products in the warehouse, including traceability controls;

iii) description of the production processes selected for review, and the rationale for the selection of the processes;

iv) description of the records reviewed for the selected production processes;

v) evaluation of records of maintenance, calibration and incoming inspection relevant to the selected production process(es);

vi) verification that the selected process has been validated if the result of the process cannot be fully verified, that the validation demonstrates the ability of the process to consistently achieve the planned result, and in the event changes have occurred to a previously validated process, that the processes were reviewed and evaluated, and re-validation performed where appropriate;

vii) If product is supplied sterile, confirmation that the sterilization process is validated, periodically re-validated, and records of the validation are available, that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions, and that the sterilization process and results are documented and traceable to each batch of product;

viii) if product needs to be reworked, prior to rework being authorized, confirmation that the organization has made a determination of any adverse effect of the rework upon the product, verification that the rework process has been performed according to an approved procedure, that the results of the rework have been

documented, and that the reworked product has been re-verified to demonstrate conformity to requirements;

ix) verification and description of the utilities (e.g. environmental conditions – air treatment, water treatment, compressed gases) and their validation, maintenance and monitoring status;

x) evaluation of environmental controls inside the production areas (e.g. cleaning of the areas, room qualifications, differential pressure, non-viable and viable particle count, etc.);

xi) evaluation and description of the product release process;

xii) if installation activities are required, verify whether records of installation and verification activities are maintained; and

xiii) verification that servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures.

- Purchasing:

i) description of the supplier evaluation files selected for review, and the rationale for the selection of the suppliers for review;

ii) verification that suppliers are selected for use by the organization based on their ability to supply product or services in accordance with the organization's specified requirements; and that the degree of control applied to the supplier is commensurate with the significance of the impact of the supplied product or service on the quality of the finished device, based on risk;

iii) confirmation that the controls defined for the verification of purchased medicinal substances, or purchased tissues, cells or substances of animal or microbial origin have been implemented by the manufacturer. (e.g. GMP for medicinal substances, ISO 22442 for animal origin); and

iv) confirmation that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.

The following should also be documented in the report and may be included in a relevant audit summary or, where suggested, under a separate heading:

a) Description of Major Changes

The report should describe when an audited activity or process has been subject to a major change. This includes major changes to products or processes, changes to the organizational structure or ownership, changes to key personnel and facilities and to the QMS as a whole. The description of these changes should include an assessment of whether regulatory requirements have been satisfied, or continue to be satisfied, and whether required regulatory submissions were made when necessary.

b) Obstacles

The report should record any circumstance where an auditor requested information and the audited organization refused to provide the information or refused to grant the auditor access to premises for audit. The report should record any other obstacles encountered that have the potential to impact the validity of the audit conclusions.

Alternatively, the report may describe these obstacles in section 2.3.4 d) - Reliability of Audit.

c) Follow-up on Past Nonconformities

When an auditor verifies the implementation of corrections and/or corrective actions stemming from past nonconformities, the results of the verification should be included in the audit report, either as part of the Audit Summaries section or under a separate heading.

The report should record any outstanding nonconformity from a previous audit as a repeat nonconformity.

d) Nonconformities

The audit report should include, for each nonconformity: a brief description of the nonconformity, a statement of nonconformity (when a requirement has not been fulfilled), the requirement against which the nonconformity is raised and the supporting objective evidence. If documented in a separate section elsewhere in the report these items should be uniquely referenced in the appropriate audit summaries. When a separate nonconformity form is used by the Auditing Organization that contains the specified information, the form may be attached to the report in lieu of these reporting requirements.

The audit report should record any unresolved objections by the organization to the issued nonconformities.

Where the audited organization undertakes cause analysis, correction or corrective action before the end of the audit, the report may record these activities; however, it does not eliminate the need to record the nonconformity.

e) Areas Not Audited

The report should record when areas that are within the scope of the audit (as defined in the audit plan) are not audited or not sufficiently audited.

2.3.4 Conclusions

The audit report should provide clear conclusions about the conduct of the audit and its overall outcome and results. The conclusions provided in this section should relate to the QMS as a whole and should cover the following:

a) Conformity with Audit Criteria

The report should include a brief summary and conclusion regarding the conformity of the QMS as implemented and addressing each set of audit criteria in 2.3.2 b) above.

b) Effectiveness

The report should include a brief summary and conclusion regarding the effectiveness of the QMS in meeting quality objectives.

c) Confirmation of Audit Objectives

The report should record whether the audit achieved the objectives in 2.3.2 c).

The report should explain why the audit did not achieve all of its objectives, if applicable.

d) Reliability of Audit

The report should outline any factors encountered that may decrease the reliability of the audit. This may include such factors as a shortfall in auditor time, the absence of the required technical competence in the audit team, or any obstacle not mentioned under 2.3.3 b).

e) Recommendations

The report should record recommendations made by the audit team with regards to the initial or continuing certification/MDSAP suitability of the quality management

system, together with any conditions or observations; as well as any other follow-up actions by the AO including changes to the audit program, changes to the composition of the audit team, or changes to the number of auditor-days projected as necessary for future audits.

2.3.5 Identification and Dating

The final audit report should include the name(s), titles, and affiliation of the author(s) of the report. The report should also be dated on its final date of issue and include version control information where necessary.

3.0 Bibliography

ISO 9000:2015 Quality management systems - Fundamentals and vocabulary

ISO/IEC 17000:2005 Conformity assessment - Vocabulary and general principles

IMDRF/MDSAP WG/N3 (2nd Edition) - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

IMDRF/MDSAP WG/N4 - Competency and Training Requirements for Auditing Organizations

3.0 Document History

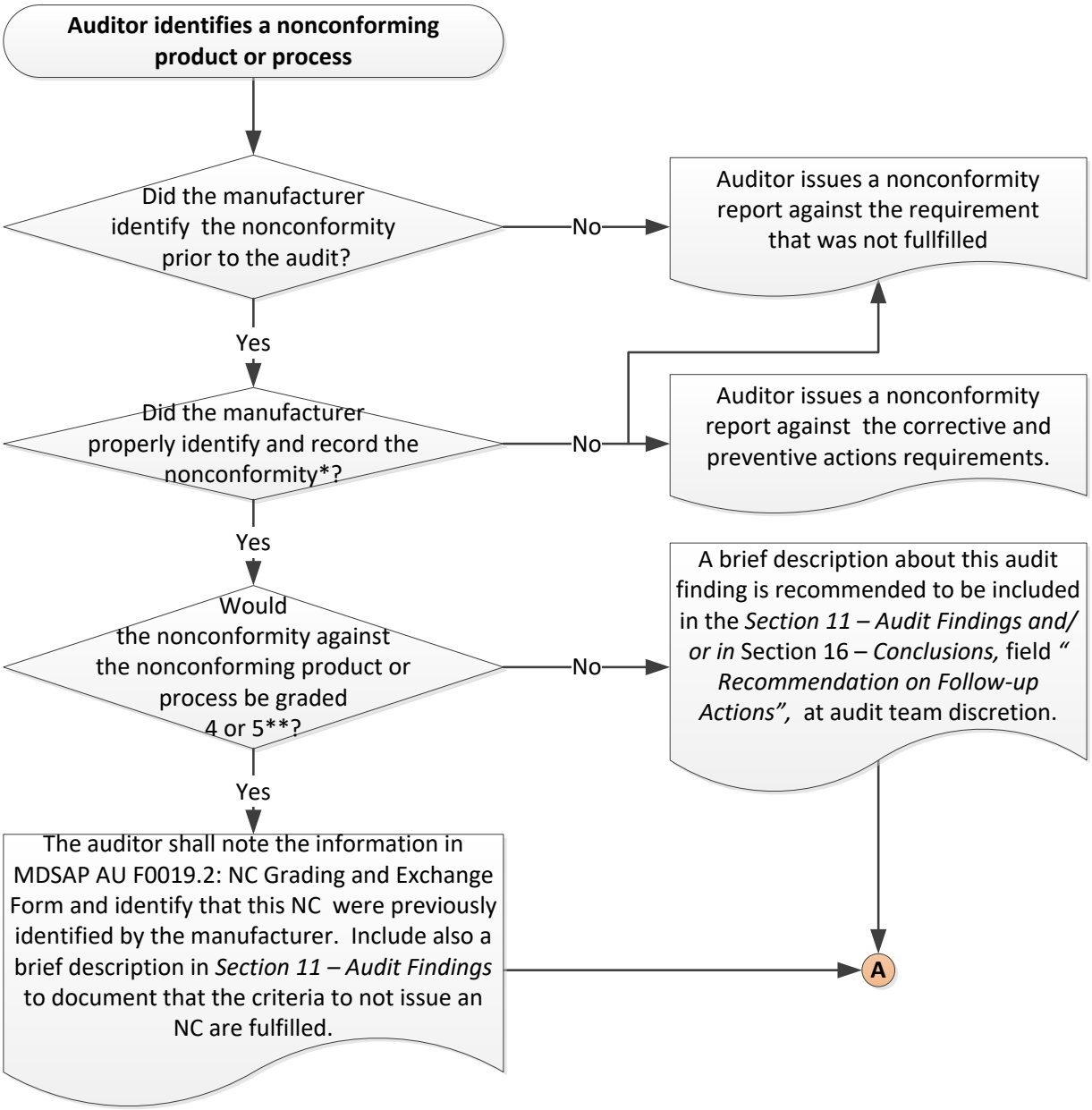
Version No	Version Date	Description of Changes	Author/Project Manager
001	2013-08-09	Initial Release	Marc-Henri Winter, FDA
002	2015-10-07	Page 2 first paragraph was updated to add Japan regulation info. Page 7-section f) Scope of Certification/ Note: added after “Brazil and/or Japan” and delete the word “ANVISA” before registration number.	Liliane Brown, FDA

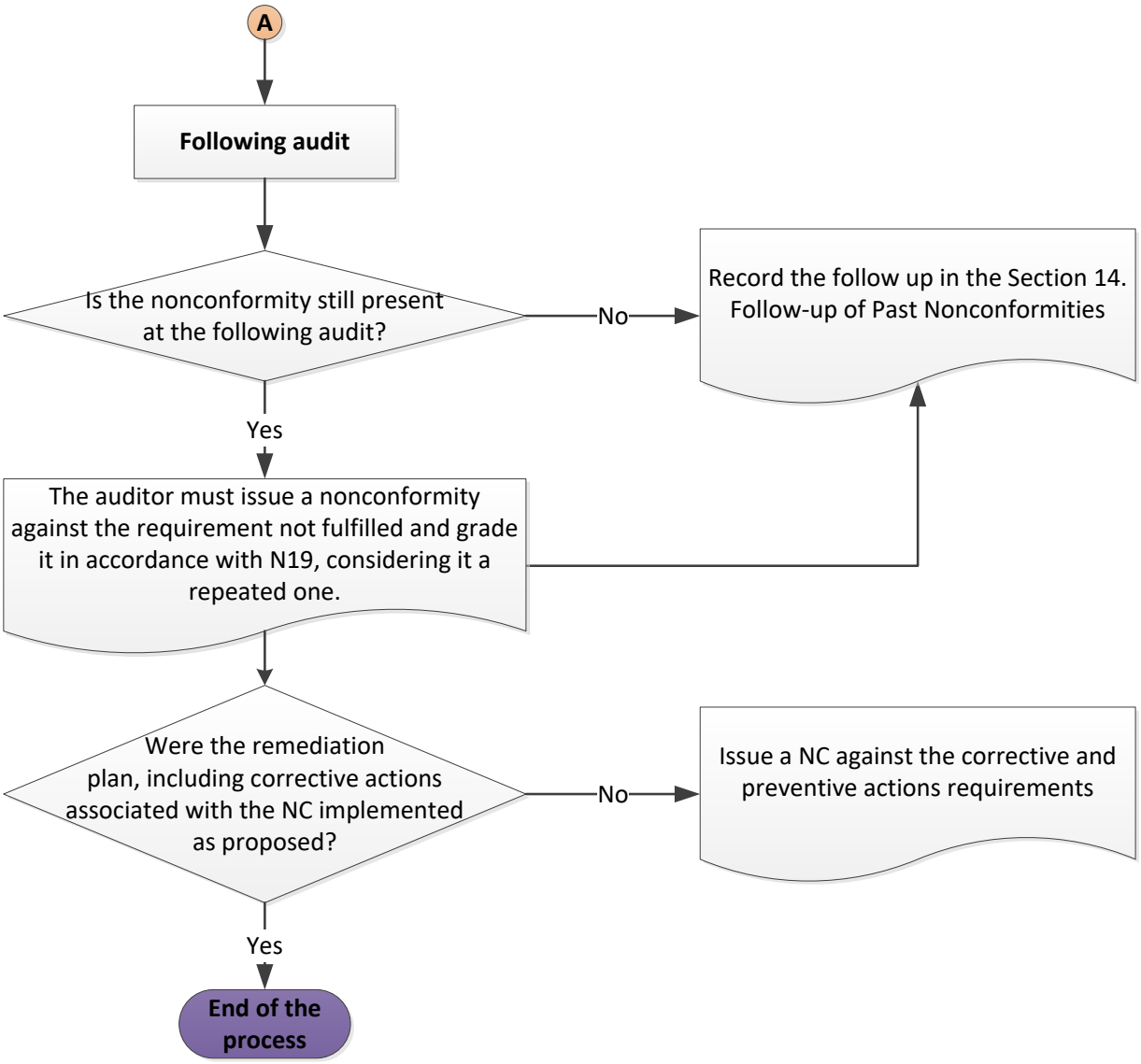
		Page 10-12 section 2.3.3: added policy statement on how to handle nonconformity independently identified by the audit team and previously identified by the manufacturer. Page 14-section vii) added the word "JP" after pharmacopeia. Page 22-23 Annex: new flowchart on the handling process of nonconformity independently identified by the audit team and previously identified by the manufacturer.	
003	2015-08-15	ISO 17021:2015 was revised and therefore this document was updated to reflect those changes throughout the document. Only minor changes were made page 11, 12, and 20 - IMDRF/MDSAP WG/N3 (*Edition 2*) clauses 8.6.2, 8.6.4, 9.5.3; including MDSAP AU F0019.2 and MDSAP AU P0027 by deleting the version control.	Liliane Brown, FDA
004	2018-03-02	Page 8 section 2.3.2 c) Audit Objectives was revised to align with IMDRF/MDSAP WG/N3 (*Edition 2*) clauses 9.3.3, 9.6.2 and 9.6.5.	Hiromi Kumada, PMDA

Version 004
Approval

Approved: Signature on file Date: 2018-03-02
Team leader for CHAIR, MDSAP RAC

Appendix – Flowchart on how to handle nonconformities previously identified by the device manufacturer and under process of remediation




A
Following audit
Is the nonconformity still present at the following audit?
No
Record the follow up in the Section 14. Follow-up of Past Nonconformities
Yes
The auditor must issue a nonconformity against the requirement not fulfilled and grade it in accordance with N19, considering it a repeated one.
Were the remediation plan, including corrective actions associated with the NC implemented as proposed?
No
Issue a NC against the corrective and preventive actions requirements
Yes
End of the process

* the manufacturer **properly identified and recorded** the nonconformity if:
- the nonconformity was documented and investigated according to the manufacturer's QMS;
- the remediation action plan, including corrections and corrective actions, as appropriate, had been defined and authorized, and had been or is being implemented, according to a specified timeframe;
- the specified timeline for implementing the planned remediation actions is respected and consistent with the significance of the nonconformity and the nature of the planned remediation actions;
- the manufacturer has a process to assess the effectiveness of the remediation actions implemented; and,
- all corresponding requirements of ISO13485:2016 Clause 8.5.2 and 8.5.3 relating to corrective and preventive action, and, any additional requirement of a participating regulatory authority relating to corrective and preventive action, have been fulfilled.

** Particular attention should be paid to situations where nonconforming or potentially nonconforming devices have been released by the manufacturer due to a nonconformity with the requirements for design or manufacturing, or where the device may not be able to maintain a state of conformity throughout its labelled lifetime due to latent design or manufacturing nonconformities (GHTF/SG3/ N19:2012 - Grade 4 or 5 NCs).