Guidance Document Title: MDSAP Medical Device Regulatory Audit Report Policy
Document No.: MDSAP AU P0019.005
Version Date: 2024-02-21

1. Purpose/Policy

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 issued by MDSAP-recognized auditing organizations in support of the Medical Device Single Audit Program are to comply with this policy. 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 (2nd Edition) - Competency and Training Requirements for Auditing Organizations*, as well as other applicable MDSAP procedural and guidance documents (per IMDRF/MDSAP WG/N3 – 6.1.4).

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2. Scope

2.1 Scope and Application

The scope of this policy document is limited to the information that participating MDSAP Regulatory Authorities expect in medical device regulatory audit reports for all audits other than Stage 1, but including special and unannounced audits.

It specifies the format and information necessary for participating MDSAP regulatory authorities to effectively use the audit reports in accordance with their legislation.

This document applies to all MDSAP-recognized auditing organizations.

2.2 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 the work products from MDSAP for different purposes. 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 by 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.

3. Definitions/Acronyms

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.
[SOURCE: IMDRF/MDSAP WG/N3 (2nd Edition)]

Campus

Either:

a. A group of locations within a maximum range of one kilometer, OR

b. A group of geographically close locations (within 60-minute drive), if not more than one of these locations would require a location-specific Regulatory Authority-issued certificate (such as the issuance of a GMP Certificate (ANVISA) or a Registration Certificate (PMDA))

In either case, the locations in the group shall be operated by the medical device organization under a single QMS. The management for, and the activities within, the group of facilities must correlate to the realization of the finished medical devices included in the scope of certification.

A campus is considered a single facility.

Notes:

1. A group of buildings sharing the same street address (same street and number) is seen as a single facility and not as a campus.
2. A campus may include multiple addresses, each with their own Regulatory Authority-issued facility identifier (e.g. FEI issued by the FDA).

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).

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.

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

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.

[SOURCE: GHTF/SG1/N055:2009, 5.1]

Scope of Certification

The type of activities, products and services as applicable to the organization's quality management system, across the organization and at each site, that is or is to be identified in certification documents. (derived from 17021-1:2015 Clause 8.2)

Scope of Audit

A description of the extent and boundaries of the audit at the audited facilty, including physical locations, organizational units, activities and processes to be audited.

(Adopted from ISO 9000:2015 3.13.5)

4. Authorities/Responsibilities

Regulatory Authorities are responsible for

a) The oversight of audits that are conducted in accordance with MDSAP, including ensuring adherence to this policy and all other relevant MDSAP policies, procedures and guidances,

b) The of audit reports and other audit deliverables for making regulatory decisions according to each regulator's processes.

Auditing Organizations are responsible for generating, reviewing and sharing MDSAP audit reports and associated documents, in accordance to this policy and all other relevant MDSAP policies, procedures and guidances.

5. Procedures

5.1 Report Format

The report must be generated using the fillable Medical Device Regulatory Audit Report (AUR) form – MDSAP AU F0019.1.

When the audit identified nonconformities, these nonconformities are to be recorded in the Nonconformity Grading and Exchange (NGE) form – MDSAP AU F0019.2. and the corresponding information imported into the audit report form (section 12).

When a multi-facility audit is necessary to maintain a manufacturer's certification, the audit team will produce a report for each facility.

All sections and fields of the audit report that are relevant to an audit should be completed. However, a section or a field that is not relevant to an audit – for example in the case of a special or unannounced audit – can be left blank or marked as not audited.

5.2 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. Past tense is used to convey what was observed at the time of the audit.

5.3 Report Content

The audit report should contain the following:

5.3.1 Information about the Audited Facility

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

a) Audited Facility's Name and Address: The name and address of the facility subject to the audit, as it would appear on a certification document.

b) Facility Identification Number: The audited facility's identification numbers, including:

- the Facility ID generated by the Regulatory Exchange Platform – secure (REPs)
- identifiers assigned by each of the participating regulatory authorities, unless they cannot be determined.

For example, 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 the case of Australia, facility identification numbers are not generated until an Australian Sponsor makes an application for inclusion of a medical device in the Australian Register of Therapeutic Goods (ARTG). In such cases, a notation of 'N/A' or 'not applicable' should be made.

c) Corporate Identity of the Organization, including:

- The legal name of the facility and, where applicable, other trade names or identities for the facility;
- As applicable, the manufacturer, if the audited facility is not the certification holder;
- As applicable, any other facility included in the scope of certification and other than the certification holder;
- Any relationships with other separate entities, including holdings, headquarters, subsidiaries, acquisitions, business units, and joint ventures that would be relevant to the certification. When preparing this section, auditors should comprehensively explain the relationship between the facility's legal entity and other legal entities within the scope of the audited facility's QMS,

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

d) Date of the last audit at the facility.

If this was the initial audit of the facility, this must be stated in the report.

e) Description of the audited facility, including:

- the approximate number of employees and associated number of shifts.
- an overview of the activities and processes carried out by the audited facility
- the identification of key outsourced activities.

- the name and title of senior management of the audited facility. Senior management includes the most responsible individual for the facility being audited as well as those responsible for establishing, implementing, and maintaining the quality management system.

The report should also identify all locations when manufacturing activities involve more than one facility and provide a description of the relationships between the facilities, their relative roles, including any shared functions, and the activities and devices, or components, associated with each facility.

When an audit was performed for a facility that was not the certification holder, the audit report must clearly reference the certification holder and the relationship of the audited facility to the certification holder.

When a multi-site audit was necessary to maintain a certificate holder's scope of certification/MDSAP suitability, a report of each audited facility is to be generated. The report of each audited organization will clearly reference the certification holder and the relationship of the audited facility to the certification holder. This will allow all reports generated to be easily assembled to support a certification/MDSAP suitability decision.

The audit of separate buildings within the same physical campus is not considered a multi-facility audit.

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

f) Scope of Certification

A description of the activities and a list of the generic medical device groups or families that were included in the scope of certification. The report may refer to an attachment when the scope of certification, or a list of devices for each jurisdiction, was extensive.

Note: If the manufacturer exports products to Australia, 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 attachment.

In the context of a multi-facility organization, the report will mention both the overall organization's scope of certification and the facility-specific sub-scope as in the certification documents.

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 attachment that must be submitted as part of the audit report package.

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 facility was supplying, or intended to supply medical devices, and claimed regulatory compliance.

In the context of a multi-facility organization, the applicable jurisdictions are generally the same to all the facilities in the scope of certification, except if a facility is only involved in activities related to devices that are being distributed – or intended for distribution – in only a subset of the jurisdictions applicable to the overall organization.

j) Exclusions and Non-Applications of MDSAP Requirements

The report should identify when the audited organization has claimed an exclusion or non-application of an MDSAP requirement, a requirement of ISO13485, or has claimed an exclusion from the requirements of jurisdictions where the manufacturer does not intend to market their devices.

5.3.2 Information about the Audit

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

a) Audit Scheme(s)

When an audit evaluated the conformity of a quality management system under MDSAP as well as under other audit or certification schemes (e.g. CE Marking), the auditing organization may chose to either use the MDSAP audit report form to record the findings under every applicable audit scheme, or generate multiple reports. The MDSAP audit report is to specify the audit schemes documented in that report, and whether separate reports were generated to document the findings under audit schemes applicable to the audit not recorded in the MDSAP audit report.

b) Audit Type

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.

c) Audit Criteria

MDSAP Audit Criteria normally includes, as a minimum, ISO 13485 and the applicable regulatory requirements for the jurisdictions to which the facility was supplying, or intends to supply.

d) Audit Objectives

Audit Objectives should refer to, as applicable, the requirements of IMDRF/MDSAP WG/N3 (2nd Edition) clauses 9.3.3, 9.6.2 and 9.6.5, for 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. Further guidance on the audit of technical documentation is provided as an appendix to the Audit Approach. 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 a participating Regulatory Authority)

e) Audit Scope

A description of the extent and boundaries of the audit, such as physical locations (sites), organizational units, and in the case of a surveillance audit, the activities and processes to be audited.

The following list contains additional items that might need to be addressed when determining the audit scope:

- complaints received by the certification body about the client;
- combined, integrated or joint audit
- changes to the certification requirements;
- changes to legal requirements;
- changes to accreditation requirements;
- organizational performance data (e.g. defect levels, key performance indicators data);
- relevant interested parties' concerns.

f) Audit Dates

The dates of the on-site audit and the duration in Auditor-days to account for the

effort of all audit team members.

g) Identification of the Audit Team

The identity of all members of the audit team (name, title, affiliation – AO employee or external resource) and describe their respective role (e.g. team leader, technical expert, etc.), the identity of any interpreter and any observers, and their affiliation.

h) Audit Language

The report should indicate the language or languages used during the audit. All audit reports must at least be available in English.

i) Stage 1 Audit Results

Reports of initial audits and, where applicable, re-audits should include the results of the Stage 1 audit activities or be attached to the report (e.g. documented findings, audit report, etc.). When elements of Stage 1 and Stage 2 audits were combined during a single on-site audit of the manufacturer, the report should include a statement as to whether all Stage 1 and Stage 2 requirements were audited.

j) Audit Plan

An attachment to the audit report, specifying the arrangements made ahead of the audit. The audit report should also document and explain any deviations from the audit plan.

5.3.3 Audit Findings

Audit findings, both positive and negative, are to be sufficient 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.

Audit Summaries - Generalities

Written summaries of the audit of each applicable MDSAP process, or activity audited, are to be included in the report.

Findings and Observations are 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.

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 was required to be audited for the audit type (e.g. initial, surveillance, re-audit), and was not

audited, the report should contain the rationale for not auditing the process.

The audit summaries should be brief but nonetheless include the following information:

a) description of the QMS process or activity audited; including whether any major changes were observed. This narrative is intended to describe the extent to which requirements were fulfilled. Consequently, the auditor should explain the context and evaluate what was observed and include sufficient audit findings, both positive and, if applicable, negative, in relation to the requirements of the QMS standard, the salient requirements of relevant process standards that are critical for ensuring that products meet specifications, and any specified requirements of a participating regulatory Authority. The narrative must provide evidence that can be proven to be true and support the audit conclusions made in the report;

b) description of the area (physical or organizational) of the site visited;

c) key documents reviewed (procedures, work instructions, etc.); Only documents that were evaluated at the time of the audit should be identified. Narratives may use a general description of the documents that support observations or findings. Detailed references (document numbers, titles and versions) should be identified in the section for “Key documents reviewed and related to this specific process or task”;

d) name and title of persons interviewed ;

e) identification of the products or components relevant to the process or activity audited; and,

f) concluding statements regarding whether the activity or process under audit was in conformity with the audit criteria, or the extent to that conformity, and meets the objectives of the MDSAP process.

Note: the inclusion of relevant references (clause numbers from standards, legislative references or MDSAP process task numbers) in the concluding statements can assist with demonstrating appropriate coverage.

Audit Summaries – MDSAP Process specifics

The audit report should also include the following MDSAP process specific information in an audit summary, as applicable considering the audit plan for the audited facility. It should document the review of the process, and record how a state of conformity or nonconformity was determined.

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Management Process:

a) 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, to address:

- which critical processes were outsourced (e.g. design and development, production processes, virtual manufacturer, Brazilian importer)
- Whether the audited facility's QMS includes appropriate controls over the outsourced processes.

NOTE: Detailed description of the audit findings on the controls of outsourced processes and review of supplier files should be recorded in the Purchasing section of the audit report.

b) verification that management reviews were 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, to include details on:

- whether the management review meets the requirements in ISO 13485:2016: 5.6.1 and 5.6.3 for inputs and outputs
- the dates the reviews were conducted whether all required attendees were present.

c) description of the organizational structure and verification as to whether the responsibilities and authorities (e.g., management representative) were established;

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

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

f) verification that the organization had the proper controls in place to ensure that only products with proper market authorization were distributed to the participating jurisdictions, to include details on methods by which the organization controls distribution of products (e.g. different product codes or skus for different jurisdictions, controls in enterprise resource planning systems)

NOTE: Detailed audit findings about Device Marketing Authorization and Facility Registration should be recorded in the "Device Marketing Authorization and Facility Registration" process.

Device Marketing Authorization and Facility Registration Process:

a) determination as to whether the organization had performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP.

b) description of the marketing authorizations reviewed for products distributed to the participating MDSAP jurisdictions

c) if the manufacturer markets devices to Australia, a description of the technical documentation reviewed (see MDSAP AU P0002 MDSAP Audit Approach, Annex 1), to include description of the product that was subject to the review of technical documentation

d) the records reviewed to determine whether the technical documentation was complete

Measurement, Analysis and Improvement Process:

a) determination as to whether 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;

b) confirmation that data from these sources were 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;

c) description of the quality data sources chosen for review during the audit, and brief explanation as to the rationale for the selection of those data sources for audit;

d) determination as to whether investigations were conducted to identify the underlying cause(s) of detected nonconformities, where possible; and confirmation that investigations were commensurate with the risk of the nonconformity;

e) 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 was appropriate to the risk of the nonconformities or potential nonconformities encountered.

   This should include details on the sampling that had been used during the audit to select records for review (judgement-based sampling, statistically based sampling) and why the selected sample was chosen (e.g. higher risk, large numbers of nonconformities with the same underlying cause, etc.)

f) verification that internal audits of the quality management system were 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;

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

h) confirmation that the organization had 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.

This should include details on the sampling used during the audit to select records for review (judgement-based sampling, statistically based sampling) and why the selected sample was chosen (e.g. higher risk, large numbers of complaints with the same underlying cause, etc.)

Medical Device Adverse Events and Advisory Notices Reporting:

a) determination as to whether the organization's processes ensured that individual device-related adverse events and advisory notices involving medical devices were reported to regulatory authorities within required timeframes; and

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

Design and Development:

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

b) description of the records that were reviewed for the selected design and development project;

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

d) determination that design and development validation data showed that the approved design met the requirements for the specified application or intended use(s), to include details on:

- The validation data and reports selected for review

- The rationale for choosing the selected validation data for review (e.g. higher risk to the patient or user per the risk analysis)

e) verification that the results of validation included the presence and completeness of clinical evidence

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

- production parameters derived from process validation / revalidation were 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.
- 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) were followed.
  - for devices containing medicinal substances, requirements for storage, sampling (including retention) 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 were followed.
  - determination that controls of design and development changes, including changes to manufacturing processes affecting the characteristics of the medical devices, were subject to design and development verification and validation, as applicable, addressing new or impacted risks;
  - for products where design controls are a permitted exclusion, verification that the organization had available and is maintaining adequate technical documentation to demonstrate conformity to safety and performance requirements and other relevant regulatory requirements.

Production and Service Controls:

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

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

c) description of the production processes selected for review, and the rationale for the selection of the processes, to include details on:

- the rationale behind the selection of the process(es); (e.g. linkage from trends observed during audit of Measurement, Analysis and Improvement; high risk process, linkage from Design and Development as the process was directly related to fulfillment of the essential design outputs, etc.)
- how the process was involved in the realization of the product(s)

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

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

f) verification that the selected process had been validated if the result of the process could not be fully verified, that the validation demonstrated the ability of the process to consistently achieve the planned result, and, in the event changes had occurred to a previously validated process, that the processes were reviewed and evaluated, and re-validation performed where appropriate, to include:

- the rationale for selecting the process validation for review (e.g. higher risk process, quality data from review of Measurement, Analysis and Improvement process revealed quality problems attributed to the process, process was involved in the product realization for multiple products)
- description of the validated process
- statement as to how the process contributed to product realization

g) verification that process parameters were being monitored to maintain the status of validated processes and for product release. For example, including, however not limited to, dose audits for gamma sterilization, bioburden monitoring and method validation, critical parameters for heat sealing (pressure, temperature and dwell time), requalification of EO sterilization, parameters for viral inactivation in materials of animal origin (ISO22422-3) etc.

h) If product was supplied sterile, confirmation that the sterilization process was validated, periodically re-validated, and records of the validation were available, that devices sold in a sterile state were manufactured and sterilized under appropriately controlled conditions, and that the sterilization process and results were documented and traceable to each batch of product, to include a description of:

- The method of sterilization
- Whether the sterilization was performed on site or as an outsourced process
- Whether the sterilization validation conforms to a recognized standard, and the standard being utilized (e.g. ISO 11135, ISO 11137), or if the manufacturer was using a non-traditional method
- Controls to ensure the process continued to be performed according to its validated state during routine production (e.g. process monitoring methods and bioburden testing)

i) if product needed to be reworked, prior to rework being authorized, confirmation that the organization had made a determination of any adverse effect of the rework upon the product, verification that the rework process had been performed according to an approved procedure, that the results of the rework had been documented, and that the reworked product had been re-verified to demonstrate conformity to requirements;

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

k) evaluation of environmental controls inside the production areas (e.g. cleaning of the areas, room qualifications including ISO classification if applicable, differential pressure, non-viable and viable particle count, etc.)

   This should include a description of pest control activities if products were marketed to Brazil

l) evaluation and description of the product release process including details on:

   - the final acceptance activities that were conducted before release for distribution
   - the person or department responsible for conducting and approving the final acceptance activities
   - the records showing the product had met the required release activities
   - A retention sample of the finished device is retained for combination medicine devices.

m) if installation activities were required, verify whether records of installation and verification activities were maintained; and

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

Purchasing:

a) description of the supplier evaluation files selected for review, and the rationale for the selection of the suppliers for review (e.g. higher risk supplied product, quality data sources from review of Measurement, Analysis and Improvement indicated quality problems with the supplied product, suppliers that provide products that directly affect product realization);

b) verification that suppliers were 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 was commensurate with the significance of the impact of the supplied product or service on the quality of the finished device, based on risk;

c) confirmation that the controls defined for the verification of purchased medicinal substances, or purchased tissues, cells or substances of animal or microbial origin

had been implemented by the manufacturer. (e.g. GMP for medicinal substances, ISO 22442 for animal origin); and

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

Audit Summary - Additional

The following should have also been documented in the report and 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 had 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 had 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 had the potential to impact the validity of the audit conclusions.

Alternatively, the report may describe these obstacles in section 5.3.4 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

Nonconformities must be recorded as required per MDSAP AU P0037 in the Nonconformity grading and Exchange (NGE) for MDSAP AU F0019.2.

The audit report should record any unresolved objections by the organization to the issued nonconformities (in section 13 of the audit report form).

Where the audited organization undertook cause analysis, correction or corrective

action before the end of the audit, the report may record those activities; however, it does not eliminate the need to record the nonconformity.

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 NGE form and in the audit report.

During the course of an audit, the audit team may independently identify a requirement that was not fulfilled and that had 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 were being implemented, according to a specified timeframe;
- the specified timeline for implementing the planned remediation actions was respected and consistent with the significance of the nonconformity and the nature of the planned remediation actions;
- the manufacturer had a process to assess the effectiveness of the remediation actions implemented; and,
- all corresponding requirements of ISO 13485:2016 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, were being fulfilled.

A NC against the corrective and preventive actions requirements should be considered in cases of previously identified issues that had not been properly addressed. The flowchart diagram in the Appendix presents the relevant decision steps.

Whenever a NC was independently identified by the audit team, the auditors should utilize the grading scheme as established in GHTF/SG3/N19:2012 (with MDSAP AU P0037) to determine the NC grade, and verify if the actual criticality of the NC was properly assigned by the manufacturer. In this evaluation, the auditor shall not consider NCs that had 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 to clearly identify that this NC was previously identified, recorded and was being appropriately handled by the manufacturer. In this case, the auditor shall also include a brief description in *Context and Significance* to document that all above criteria were 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, had been released to the field.

NOTE 1: Particular attention should be paid to situations where nonconforming or potentially nonconforming devices had been released by the manufacturer due to a nonconformity with the requirements for design or manufacturing, or where the device may not have been 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 were 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 was under remediation, was previously identified and appropriately recorded by the manufacturer, fulfills all the requirements mentioned above, and was 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 *"Recommendations 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 MDSAP AU P0037. 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.

Refer to the Appendix for a flowchart on how to handle nonconformities previously identified by the device manufacturer.

e) Areas Not Audited

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

5.3.4 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 5.3.2 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 5.3.2 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 5.3.3 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.

5.3.5 Author and Date

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.

6. Forms

MDSAP AU F0019.1 – Medical Device Regulatory Audit Report

7. Reference Documents

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 (2nd Edition) – Competency and Training Requirements for Auditing Organizations

MDSAP AU P0002 MDSAP Audit Approach

MDSAP AU P0037 Guidelines on the use of Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange (GHTF/SG3/N19:2012) for MDSAP purposes

8. Document History

Guidance Document Title: MDSAP Medical Device Regulatory Audit Report Policy
Document No.: MDSAP AU P0019.005
Version Date: 2024-04-26

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/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. 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.	Liliane Brown, FDA
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*)	Hiromi Kumada, PMDA

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VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
		clauses 9.3.3, 9.6.2 and 9.6.5.	
005	2024-02-21	Adjusted format of the document Added definition of Campus in section 3 Added clarifying text under 5.3.2 on the use of the audit report form in the context of multi-scheme audits. Added clarifying text under 5.3.3 “Management” to include detail on documenting extent of outsourced processes, management review, and controls to ensure appropriate marketing of products to the correct jurisdictions Added text to clarify audit report documentation of review of technical documentation in section 5.3.3 under “Device Marketing Authorization and Facility Registration”, page 14 Added text to clarify audit report documentation for rationale for selecting quality data sources in section 5.3.3 under “Measurement, Analysis and Improvement” Added text throughout to clarify audit report documentation in section 5.3.3 “Design and Development” Added text to clarify audit report documentation in section 5.3.3 (iii) though (xii) under “Production and Service Controls Replaced the term “organization” with “facility” throughout the	Marc-Henri Winter, FDA

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VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
		document Added reference to MDSAP AU P0037	

Version Approval: 005

Approved: Signature on File, CHAIR, MDSAP RAC

Date: 2024-04-26

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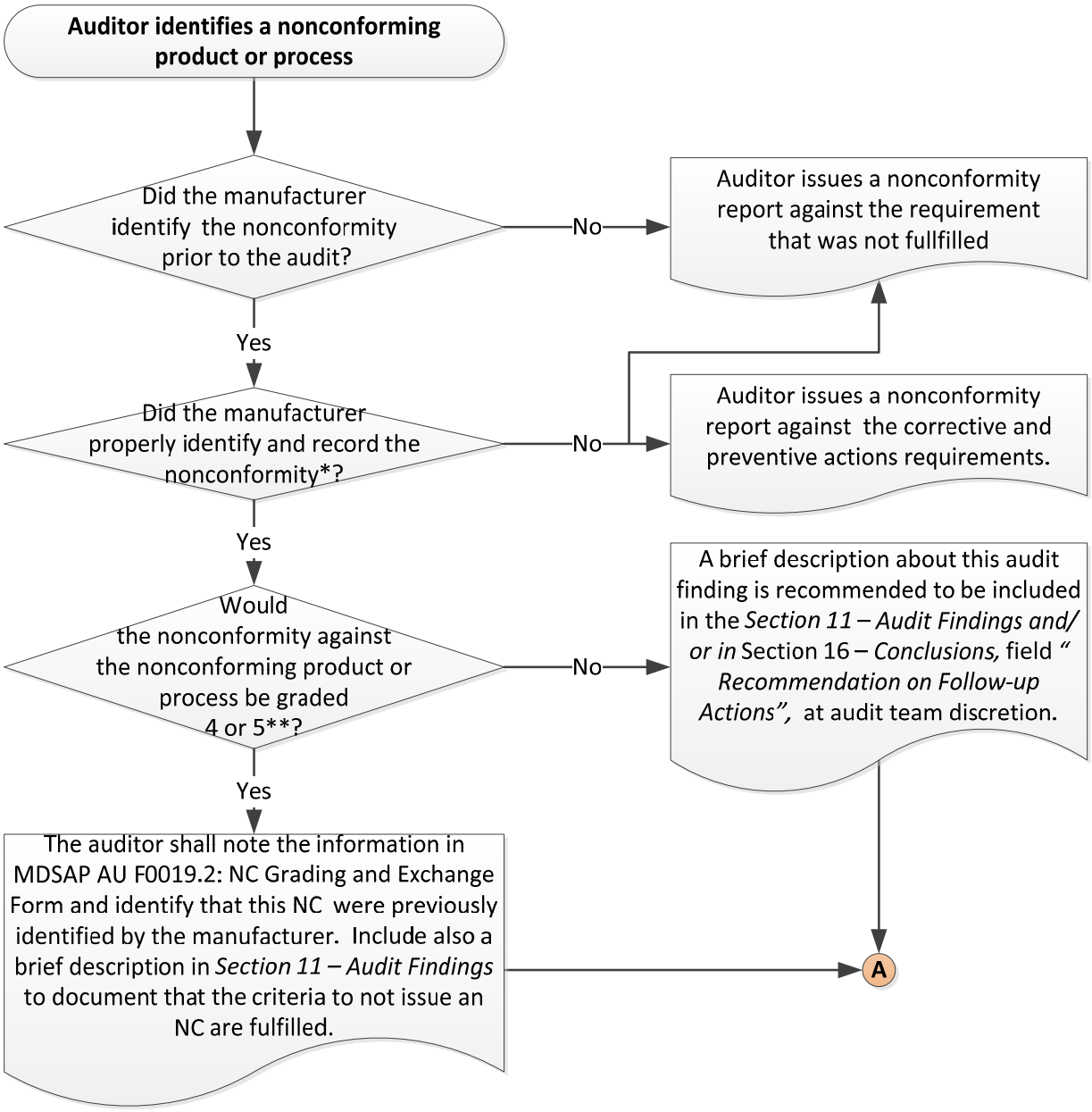
Appendix – Flowchart on how to handle nonconformities previously identified by the device manufacturer and under process of remediation



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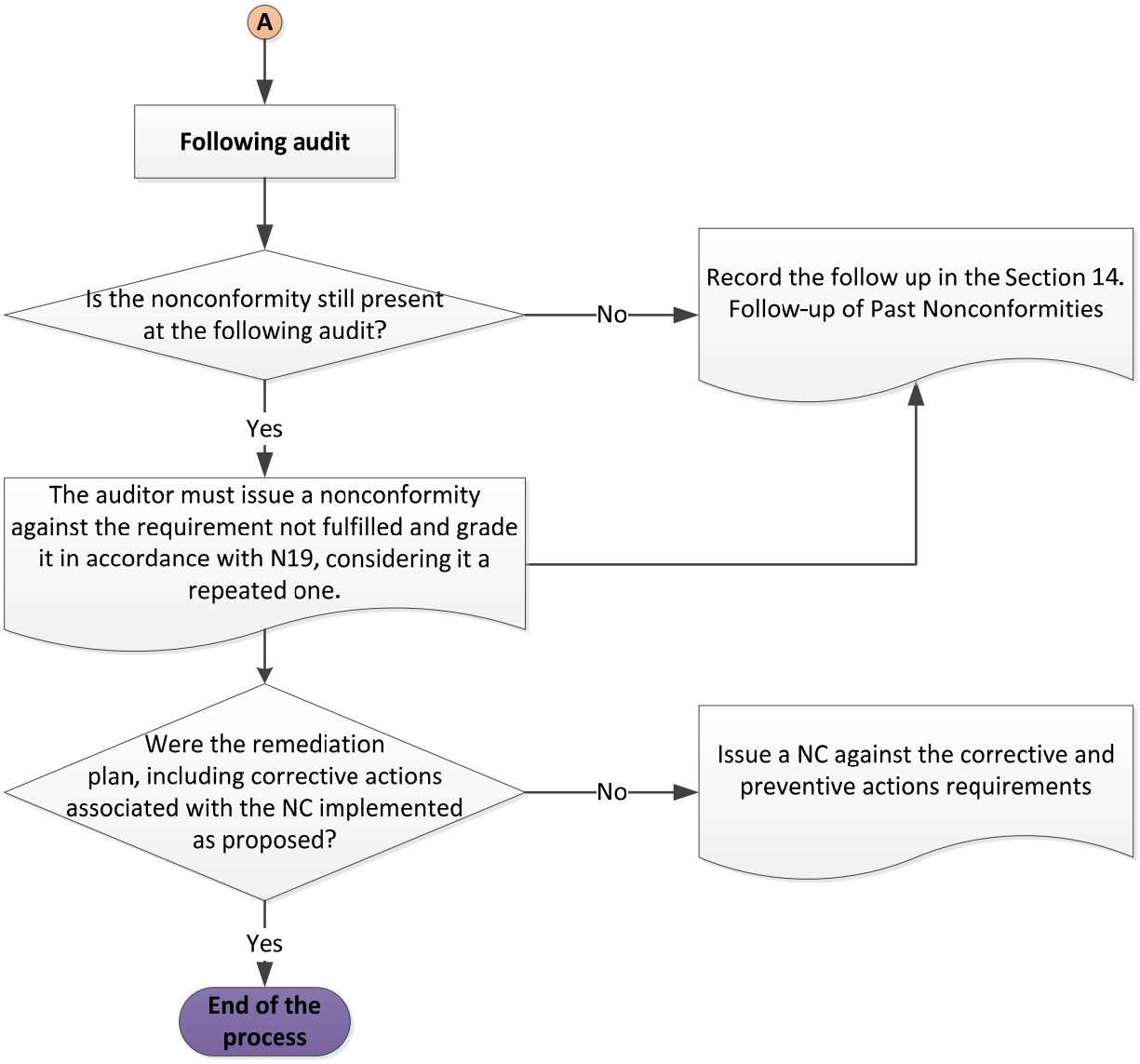

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* the manufacturer **properly identified and recorded** the nonconformity if:
- the nonconformity was documented and investigated according to the manufacturer's QMS;
- the remediation action plan, including corrections and corrective actions, as appropriate, 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).