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Regulatory Agency Factory Audits – Roles and Responsibilities

Document Number and Revision: 7326060 Rev 06

Overview

This document details the roles and responsibilities of Oracle and manufacturers of Oracle Systems products to support these routine factory audits and product tests for product certifications obtained by Oracle. This document does not cover requirements for JDM products where the JDM has obtained all product certifications

Audience

Contracted External Manufacturers, Internal Manufacturers, Oracle Compliance/Safety Engineering, Global Business Unit (GBU) Compliance

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1. Introduction

Certifying regulatory safety agencies require routine factory audits of manufacturer to maintain product safety certifications on Oracle products. These routine audits may include requirements for product and/or component tests. The intent of these factory audits is to confirm products built at the factory still comply with the product safety certification requirements and have not deviated as a result of the production processes and/or procedures. This document details the roles and responsibilities of Oracle and manufacturers of Oracle products to support these routine factory audits and product tests for product certifications obtained by Oracle. This document does not cover requirements for JDM products where the JDM has obtained all product certifications.

2. Reference Documentation:

- **3092:** Product Safety Marking and Requirements for Components and Materials (found on AQP)
- **923-7024076-XX:** WWOPS Test Hipot – Oracle Directed Instrument Settings for Routine Electrical Safety Testing in Production (found on AQP)
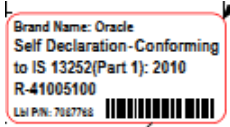
3. Definitions:

ACRONYM	DEFINITION
AQP	Advanced Quality Planning. A matrix with Oracle specifications/documents that provide Manufacturing and Operations requirements. The matrix 913-3592 can be accessed in the Fusion Product Development module.
BIS	Bureau of India Standards – government agency that provides India registration of equipment.
CCC	China Compulsory Certification – certification and mark to signify product is certified to the appropriate China standards. Certifications typically include product safety and electromagnetic interference (EMI).
CQC	China Quality Certification (Centre) China Quality Certification Centre (CQC) is a professional certification body under China Certification & Inspection Group (CCIC) approved by State General Administration for Quality Supervision and Inspection and Quarantine and Certification and Accreditation Administration of the People's Republic of China. CQC issues CCC certifications and performs routine factory follow-up inspections.
JDM	Joint Development Model products are those where Oracle contracts portions of the engineering design work to a supplier. These products are offered for sale under Oracle's brand name, but the design qualification work and agency approvals are provided by the supplier.
NRTL	Nationally Recognized Testing Laboratory. Organizations recognized by US OSHA to provide product safety testing and certification services on products to ensure they meet the requirements of construction and general industry OSHA electrical standards and appropriate product safety standards. After certifying, the NRTL authorizes the manufacturer to apply their registered mark to the product(s).

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| TUV Rheinland of North America | NRTL that tests and certifies products/components to North America and International product safety standards. Issued mark of conformity is considered equivalent to NRTL marks issued by TUV SUD America and Underwriters Laboratories. |
| Underwriters Laboratories (UL) | NRTL that tests and certifies products/components to North America and International product safety standards. Issued mark of conformity is considered equivalent to NRTL marks issued by TUV Rheinland of North America and TUV SUD America. |

4. Regulatory Agency Marks:

Below is a list of agencies and their marks that may be used on Oracle products or components (shown on the product or component compliance label). Those agencies listed below require routine factory follow-up inspections to ensure products produced at the factory continue to comply with the product safety certification requirements and have not deviated as a result of the factory production processes and procedures.

Note: Audit frequency is determined by the auditing agency.

Agency	Sample Agency Mark(s) (may be included on product Compliance Labels)	Factory Audit Frequency	Special Requirements
Underwriters Laboratories (UL) - Nationally Recognized Testing Lab (NRTL)		Once per calendar quarter	
TUV Rheinland – NRTL		Once per calendar quarter	
TUV Rheinland - EU	IEC/EN 60950-1	Once per calendar quarter	
China Compulsory Certification (CCC) China Quality Certification (CQC)		Once per year *	Component test reports to GB standards Product tests to GB standards
Bureau of India Standards (BIS)	Brand Name: Oracle Self Declaration-Conforming to IS 13252(Part 1): 2010 R-41005100 Lbl P/N: 7067768 Or	None to Date	Market Surveillance requires systems from the manufacturer's production line be sent to the specified India lab for testing/inspection to confirm products are being

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	IS 13252 (Part 1)/ IEC 60950-1 R-12345678		manufactured as originally registered.

*CQC rules are changing as of May 2015. Factory audits may be less frequent depending on the manufacturer's status/ successful CQC audits.

5. Contracted External Manufacturer and Internal Manufacturer Regulatory Agency Factory Audit Requirements:

The manufacturer is responsible to adhere to the terms and conditions in agreements with the regulatory agencies performing factory audits. Additionally, to support manufacture of Oracle certified products, the manufacturer is responsible for, but not limited to:

1. Obtaining certifying agency factory audit regulations/requirements/specifications.
2. Escort announced or unannounced certifying agency auditors to the factory production floor where Oracle products are being built for the purposes of product, process and procedure inspections.
3. Maintain calibration of test equipment required to meet routine or periodic product safety testing required by certifying/auditing regulatory agency(ies).
4. Perform 100% production line testing of Oracle products as required and specified by the certifying/auditing regulatory agency(ies). Keep test logs as required by each certifying/auditing agency.
5. When required to support certifying/auditing regulatory agency audits, provide Oracle certified products from the current production line for the purpose of EMI testing (this does not include Oracle JDM certified products). Refer to Appendix A for guidance on scheduling necessary tests.
6. Contracted External Manufacturers only: When required to support certifying/auditing regulatory agency audits, provide Oracle certified products from the current production line for the purpose of Safety testing (this does not include Oracle JDM certified products). Refer to Appendix A for guidance on scheduling necessary tests.
7. Internal Manufacturer only: Perform product-safety related systems tests (e.g. annual tests) of Oracle products where specified by a certifying, or auditing, regulatory agency.

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8. Obtain component test reports and/or certificates of conformity from suppliers required by certifying/auditing regulatory agency(ies) for the purposes of factory audits. Refer to Annex B for guidance on obtaining necessary documents.
9. Obtain material declaration documents from suppliers for verification of plastic material (manufacturer and type designations called out on Oracle drawings) molded into plastic parts procured for use in Oracle products. These material declaration documents are to be requested of and provided by the supplier of the molded plastic parts. The material declaration documents are to be retained as required by the certifying or auditing regulatory agency(ies).
10. Notify Oracle Safety Compliance Engineering when any variation notice, or audit deficiency is found by a regulatory agency (email compliance_request_ww_grp@oracle.com).   Resolve all variation notices, or audit deficiencies found during regulatory agency factory audits. This resolution must be completed within the time specified by the auditing agency. The appropriate Oracle Compliance and/or Safety Engineering personnel will assist (as appropriate) if changes to the certifying product agency report are necessary.
11. Ensure safety critical components have the appropriate markings as listed in the product safety report critical components list
12. Notify Oracle Technical Compliance Engineering Manager (email compliance_request_ww_grp@oracle.com) promptly, preferably within 2 working days of receipt, of any email or correspondence received from India BIS or other India entity (such as an India test lab) related to Oracle products. Prompt notification is required as Oracle must respond to regulatory inquiry within short timelines set by the agency. Please designate alternative contacts when you are out-of-office.

Any deviation to the above must be approved in writing by Oracle Technical Compliance Engineering Manager (email compliance_request_ww_grp@oracle.com) and the assigned Oracle Supplier Program Manager.

6. Oracle Product Safety Engineering and Product EMC-Compliance Requirements in Support of Regulatory Agency Factory Audits:

Oracle Product Safety Engineering is responsible to support regulatory agency factory audits at Contracted External Manufacturers' and Internal Manufacturers' facilities to aid in successful audits. These support responsibilities include, but may not be limited to:

1. Provide guidance, when necessary, to obtain required annual test reports/data for components that are listed as safety critical in the product safety report(s) issued by the certifying/auditing regulatory agency(ies). Refer to Appendix B for guidance.
2. Ensure product safety reports identify if sub-assemblies are to be inspected at factories other than the final assembly factory based on accessibility of the component(s) at the final assembly factory.
3. Ensure certified product regulatory agency reports (including critical component lists) are kept current and correlate to released product bill-of-materials, including all suppliers of critical components. Encourage generic listings of component manufacturers and model numbers when possible and consistent listing of components used across product lines.
4. Ensure the manufacturer has the latest version of the issued reports/certifications.

Oracle Product Safety Engineering may support at Oracle's discretion, External Manufacturers on required annual tests and/or reports of systems required by certifying/auditing regulatory agency(ies). (See item #6 above in *Contracted External Manufacturer and Internal Manufacturer Regulatory Agency Factory Audit Requirements*).

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Oracle Product EMC-Compliance Engineering may support at Oracle's discretion, regulatory agency factory audits that require any EMI audit testing of products directly certified by Oracle. This does not include JDM certified products. (see item #5 in Contracted External Manufacturer and Internal Manufacturer Responsibilities regarding tracking and notification audits)

Any deviation to the above must be approved in writing by Technical Compliance Engineering Manager (email compliance_request ww_grp@oracle.com) and the assigned Oracle Supplier Program Manager.

On-site support during certifying agency factory audits by either Oracle Product Safety Engineering or Oracle Product EMC-Compliance Engineering is at the discretion of these groups.

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7. Appendix A: Guidance for Scheduling Necessary System Tests to support Certifying/Auditing Regulatory Agency Factory Audits

Some certifying/auditing regulatory agencies (for instance, CCC/CQC) require annual tests of systems that are not covered in the normal required 100% production-line tests. This Appendix is intended to provide guidance for manufacturers on how to support those required annual system tests.

Required Annual Systems Tests:

Efficient planning for upcoming audits is critical to ensure required resources are available to perform necessary testing and to avoid surprises of any failures, allowing ample time for corrective action if necessary before the factory audit deadline. Necessary system tests are defined in the appropriate certifying/auditing agency factory audit requirements.

Guidance:

1. The Manufacturer is to identify requirements to support the next audit requiring system tests that are beyond the normal 100% production-line tests.
    a. What agency(ies) require additional system tests for audits and at what frequency (e.g. annually)?
    b. When is the next audit anticipated to take place (month/year)?
    c. What systems will be required to be tested (other than the normal 100% production line tests) to support the next factory audit?
    d. What tests will be required (EMI, Safety, etc.)?
2. Plan a test schedule to ensure 1) test requirements are met and 2) testing is spread out over the course of several months (See Note)
    a. Use the suggested form (below) to identify system test requirements and request month/year of test(s)
    b. Send a request email to compliance_request_ww_grp@oracle.com (and the suggested form with all systems listed that will need to be tested to schedule testing with Oracle over the next several months).
    c. Equipment must be received by Oracle 10 working days before any test schedule confirmed by Oracle.

   NOTE: If Oracle cannot accommodate testing during any period of the year, it is the responsibility of the manufacturer to have testing accomplished by another qualified 3rd party.

Test Request to Support Factory Audit					
Anticipated date for next _<<insert auditing agency name>>_ Factory Audit: _<<insert Month/Year>>_					
Model No.	CMN	Safety Tests required	EMI Tests required	Test Schedule Request Month/Year	Test Schedule Confirmed by Oracle lab (name/initials)
Example: X5-2	_GR1EP_	_Y_	_N_	_October/2016_	

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8. Appendix B: Guidance for Obtaining Necessary Component Test Reports to support Certifying/Auditing Regulatory Agency Factory Audits

Some certifying/auditing regulatory agencies (for instance, CCC/CQC) require annual tests of safety critical components that are not covered in the normal required 100% system-level production-line tests. This Appendix is intended to provide guidance for manufacturers on how to identify what component test data/reports may be required. If a component manufacturer is unable to provide the correct test reports per the agency(ies) requirements, it the responsibility of the Internal Manufacturer/External Manufacturer to coordinate and complete the agency test. (Fan Motor, PCB flammability, plastic burn test)

Required Annual Component Tests:

Efficient planning for upcoming audits is critical to ensure any required component test reports are obtained to support a factory audit.   Understanding the factory audit requirements through published certifying/auditing agency audit requirements and/or Agreements is required in order to ensure successful audits.

 Guidance:

1. The Manufacturer is to identify what component test reports will be required to support the next audit
    a. Identify what agency(ies) require component tests and at what frequency (e.g. annually).
    b. Determine what components are required to be tested. Refer to the certifying/auditing agency factory audit requirements and/or Agreements.
    c. Identify when the next audit is anticipated to take place (month/year).
    d. Identify what components will be required to be tested to support the next factory audit:
        i. Identify components that are listed in the certifying/auditing agency inspection report.
        ii. Identify which of those components are required to be tested to support a factory audit.
    e. Identify the suppliers of the components to be tested.

2. Request component test reports/data to the required standards
    a. It is suggested to allow for a *minimum* 4-month lead time to obtain necessary component test reports from suppliers."
    b. Requests for component test reports/data need to be made directly to the component supplier or through any other sub-tier supplier who provides sub-assemblies containing those components.

    Note: Obtaining test reports for components containing Oracle IP (such as DVDs with Oracle firmware) are supported through Oracle Supplier Program Management.   This does not include test reports for materials used to produce components with Oracle Intellectual Property.

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Related Information

Document History and Approvals

Rev	Date	Description of Change
01	12/17/2015	Initial development release
02	12/17/2015	No change to document. New development EC issued to include attachments in Agile
03	03/15/2016	Added BIS Logo in chart under section 4.0. Production release of document
04	03/02/2020	Added some verbiage in bold "Oracle Product Safety Engineering may support **at Oracle's discretion** on Section 6 and 1) test requirements are met and 2) testing is spread out over the course of several months **(See Note)** on Appendix A. Removed reference to 923-2349-XX and corrected reference document no. 923-702-4076-XX.
05	08/15/2022	Converted to Corporate Redwood format. Removed reference to Beehive. Corrected part number from 923-702-4076-XX to 923-7024076-XX.
06	2/2/24	Section 3: removed Demko and TUV SUD America. Section 4 Regulatory Marks: removed UL – EU and TUV SD America. Section 5, paragraph 10: added Safety to Oracle Compliance Engineering. Additional minor punctuation, spelling corrections.

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