Sparta Systems, Inc.
2000 Waterview Drive, Suite 300 |
Hamilton, NJ 08691
Tel: 888.261.5948 | Fax: 732.203.0375
www.spartasystems.com

AUDIT FRAMEWORK

Sparta Systems, Inc. ("Sparta") prepared this Audit Framework ("Audit Framework") to guide audit requests by customers of Sparta's quality management system ("QMS") for software products licensed or provisioned to customers. This Audit Framework applies to audits conducted onsite or remotely, as well as desktop audits. Sparta reserves the right to amend and modify this Audit Framework.

Audit Framework

- An existing customer may request an audit of Sparta Systems' QMS as it relates to the Sparta Products used by the customer under its license or service agreement.
- Sparta requires thirty (30) calendar days prior written request for any onsite or remote audits or forty-five (45) calendar days notice for desktop audits. The audit must be conducted at a mutually agreed date and time and in accordance with the Audit Framework. The audit may include ISO 9001, SOC 2, and the products' compliance to Title 21 CFR Part 11.
- Only one virtual or on-site audit at our Hamilton, New Jersey office is permitted per two calendar years and shall not exceed two business days. Anything outside of this framework will accrue a fee at the then current rate. In lieu of an onsite/virtual audit, a Desktop audit may be requested.
- Sparta subject matter experts ("SMEs") shall be limited to one hour per SME unless otherwise agreed to in the audit schedule. If additional time is needed, Sparta may request prior written consent including an additional fee at the current SME rate.
- No more than two auditors may be designated to participate in the audit unless Sparta gives prior written consent. All audits are "single threaded", and must follow the audit agenda unless approved by Sparta prior to or during the audit. This allows proper coverage by Sparta and ensures availability of their SMEs.
- No confidential documents are permitted to be copied, photographed or otherwise leave Sparta's facility.
- No access will be allowed to any information regarding other Sparta customers, Sparta's employees, or any other information which if made public would impact the security, confidentiality or integrity of Sparta's premises, network, or products.
- No tours of Sparta's facilities are permitted.
- Audits shall be conducted during Sparta's normal business hours and shall not unreasonably interfere with Sparta's normal business operations.
- To ensure expedient responses to all our customer audits, the following guidelines will be followed:
    - After the completion of the on-site or virtual Audit, the customer will send Sparta a draft audit report within two weeks of the completion of the audit. Failure to comply with this timeline, without express written permission, will result in the immediate satisfactory closure of the audit and all associated audit findings.
    - Sparta will provide the customer with feedback on the Audit Report as well as Draft Finding Responses within two weeks of receipt of the Draft Audit Report.
    - The customer will then have an opportunity to review the response and provide clarification and/or request an update within one week of receipt of the draft audit responses. Failure to comply with this timeline, without express written permission, will result in the immediate acceptance of the audit finding responses.
    - Sparta will then issue a Final Audit Response with specific actions to remediate the Audit Findings.
    - Once the Audit Findings have been issued, the scope of those findings will not be expanded.
    - Once the Final Audit Response has been issued, the scope of the remediation will not be expanded

Sparta Systems, Inc.
2000 Waterview Drive, Suite 300 |
Hamilton, NJ 08691
Tel: 888.261.5948 | Fax: 732.203.0375
www.spartasystems.com

Auditors	External Audit Team
Corporate Security and Compliance ("CSC")	Audit Lead **Email Contact information**: spartacsc@honeywell.com
Relevant standards and criteria	• ISO 9001– Independent Assessment – Reliance should be placed for Quality • Service Organization Control ("SOC") 2 Type 2 – Independent Assessed by American Institute of CPAs ("AICPA") – Reliance should be placed for Security • Title 21 CFR Part 11 **Note:** Sparta Systems is a commercial software manufacturer and, as such, is not subject to the same industry competent authority, (regulatory) oversight as many of our life sciences customers. The predicate rules of *Title 21 of the Federal Food, Drug, and Cosmetic Act* are not directly applicable to Sparta's manufacture and/or provision of our products and services. Rather, our products support and enable your compliance to *Title 21 CFR Part 11, Electronic Records; Electronic Signatures*, as they apply to your regulated quality management system(s). Sparta Systems has chosen to comply with *ISO 9001* quality management systems requirements and *SOC 2* Guidelines in response to the needs of our customers and as a good business practice.
Scope and objective of the audit	Review of Sparta's Internal QMS as it relates to Customer's Purchased Sparta Products