Determining Audit Time:

1. On the path to becoming ISO 9001 certified you will undergo external audits by Husk Registrars, LLC (certification body). Audit time is determined by the size, complexity, risk, and nature of the organization. Husk Registrars, LLC use the guidelines and requirements set forth by the International Accreditation Forum (IAF) to consider these factors and determine time required to audit clients.
The ISO 17021:2015 table below represents the guidelines provided by IAF to be used for calculating ISO 9001:2015 Audit Days based on number of employees.

Effective Number of Personnel	Audit Time Stage 1+Stage 2 (days)	Effective Number of Personnel	Audit Time Stage 1+Stage 2 (days)
1-5	1.5	628-875	12
6-10	2	876-1175	13
11-15	2.5	1176-1550	14
16-25	3	1551-2025	15
26-45	4	2026-2675	16
45-65	5	2676-3450	17
66-85	6	3451-4350	18
86-125	7	4351-5450	19
126-175	8	5451-6800	20
176-275	9	6801-8500	21
276-425	10	8501-10700	22
426-625	11	>10700	Follow Progression Above

2. When complexity, risk, and nature of the organization being audited are factored into the equation, the audit time listed in this table may be adjusted. IAF provides additional guidelines and requirements for considering these factors.
Audit time will take into account IAF MD-5 requirements for the initial, surveillance and re-certification audits. Husk Registrars, LLC could determine after an initial audit that more or less time is required for the surveillance audit.
Audit time may include remote auditing techniques such as web meetings, teleconferencing, and electronic verification of the client's processes for surveillance audits. This is not uncommon for certification bodies.

Note 1: View number of employees as continuum rather than stepped change.

Note 2: High, Medium, Low, and Limited are complexity categories. See Table EMS 2 in MD 9.

3. MD 5 states the audit duration for all types of audits includes on-site time at a client's premises and time spent off-site carrying out planning, performing document review, interacting with client personnel, and writing the report. The off-site activities should not reduce the total on-site audit duration to less than 80% of the times shown in the tables above. The audit days are based on eight hours per day. The audit days cannot be reduced by planning on longer hours per working day. MD 9 adds that the duration for ISO 13485 audits will be dependent on the audit scope, objectives, and specific regulatory requirements, as well as, on the range, class, and complexity of medical devices, and the size and complexity of the organization.

Surveillance Audits

1. During the initial three-year certification period, surveillance audits should be proportional to the time spent on the initial certification audit. The total amount of time spent annually on surveillance audits should be about 1/3 the time spent on

the initial certification audit (stage 1 + stage 2). Surveillance audit duration in future periods should take into account organizational changes and system maturity.

Re-Certification Audits

1. The re-certification audit is normally 2/3 of the time spent on the initial certification audit (stage 1 + stage 2). Future re-certification audits should be based on the time that would be required for the initial certification audit if it were to be carried out at the time of re-certification (not 2/3 of the original initial certification audit). The audit duration should also take into account the review of system performance.

Adjustment Factors

1. Increase the Days

MD 5 identifies factors to consider for possibly increasing the duration of ISO 9001 and ISO 14001 audits as complicated logistics, multiple languages, large physical site, highly regulated, and complex processes.

MD 9 states the duration may be increased for ISO 13485 audits due to the number of ranges and/or complexity of medical devices, use of critical suppliers without sufficient evidence of conformity (may have to audit suppliers), manufacturers that install products at customer's premises (may have to visit customers or review installation records), and poor regulatory compliance.

2. Decrease the Days

MD 5 considerations for decreasing the duration for ISO 9001 or ISO 14001 audits include factors such as excluded requirements, system maturity, other certifications, identical shifts, multiple sites, and low complexity. The guidance states a reduction in audit duration would be unlikely to exceed 30% of the times established from the tables.

MD 9 states that the duration for ISO 13485 audits may be decreased based on reductions of the manufacturing product range, or design and production processes, since the last audit.