

CHARGING INSTRUCTION



1. OBJECTIVE: Objective is to define charging for companies which get management system certification service from UDEM.

2. SCOPE: This instruction includes in fees of UDEM in accordance with requirements of EN/IEC 17021-1:2015 standard as service indication of servicing UDEM equally to all clients.

3. RESPONSIBLES: General Manager, Administrative and Financial Affairs Manager, Certification Manager

4. DEFINITIONS:

Man/day fee (Auditor/day fee): 1 auditor to audit for one day is wage earner. Man/day fee for UDEM is **1.000 Euros for EN ISO 13485 and 300 Euros for EN ISO 9001**

5. APPLICATION: Clients/member clients need to fill in Application Form (FRM.12,FRM.81) in order to receive price offer from UDEM.

5.1- Initial Certification Audit Fee: Applicant Company needs to determine man/day number according to number of employees of the company in accordance with related international accreditation rules in order to determine initial certification audit fee. If changes in client qualifications were realized at the end of the Stage 1 Audit, man day can be changed for Stage 2 Audit. When this is the case, it is obliged to pay fee with the difference of initial offer submitting to the client. There is one item which states clearly this situation in order to not leave someone in a difficult situation and to prevent the disagreements in Certification Offer/Agreement Form (FRM.16,FRM 16.M).

5.2- Surveillance Audit Fee: Fee of surveillance audits to be realized once a year at the least is determined depending on auditor time as for initial certification audits.

5.3.-Re-assessment Audit Fee: Fee of reassessment audits is determined according to audit time depending changes of number of employees at the end of 3 – years certification process of the client.

5.4- Pre-audit Fee: If the company demands pre-audit, fee needed to pay is **same as Stage 1 Audit**.

5.5-Follow-up Audit Fee: When required, follow-up audit fee is paid for nonconformities in audits. The follow-up audit fee is same as Stage 1 Audit fee.

5.6-Privacy Audits:

a) If the audit needs when demanding for broadening the scope, audit fee is determined for surveillance audit according to audit man/day fee. If the client approves to unite broaden the scope with surveillance audit, audit fee is determined depending on present-day conditions and client qualification.

b) Man/day fee of short-term audits is same as Stage 1 Audit fees.

5.7- Integrated Audits: Man/ day numbers are calculated separately in integrated audits and UDEM has a right of additional discounting as % 30 according to the result.

5.8- Other situations: If UDEM regards the audit in some situations such as suspending, recalling, limiting the scope of client certifications, UDEM is determined that man/day fee of the audits is same as the surveillance audit.

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Stage 1 audit time is calculated as maximum 30 % of certification audit time.

First of all, man/day time of the audit is calculated in UDEM charging implemented to the clients thank to the tables below.

5.9- Based on Article 8.1.4 in EA 2/17 M:2016 document; in the case of that manufacturer receiving conformity assessment service or authorized representative demand, making general information to them about regulation basis on assessment and costs that will arise within the services to be provided are presented to the organization requesting the information by being calculated by UDEM considering quality of given information and the time that will be spent by personnel who is authorized by UDEM for information process.

Calculated man/day time is multiplied with **1.000 Euros for EN ISO 13485 and 300 Euros for EN ISO 9001**. 100 € as application and document examination charge and number as an annual document usage fee in Table 3 are added. Found number is initial certification fee.

If audit type is surveillance audit, audit man/day time is calculated as 1/3 of initial certification audit time.

If audit type is reassessment audit, audit man/day time is calculated as 2/3 of initial certification audit time.

VAT is not to be included these charges. UDEM pays charge of transportation and accommodation of auditors and technical experts. UDEM has right to make 25% discount or addition in the amount where there is no VAT due to certain reasons.

Table 1-Auditor Calculating Chart for EN ISO 9001:2015 Certification:

<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2</u>	<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2</u>
1-5	1.5	626-875	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
46-65	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.

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Table 2 - Auditor Calculating Chart for EN ISO 13485:2016 Certification Auditors

<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2 (days)</u>	<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2 (days)</u>
1-5	3	626-875	15
6-10	4	876-1175	16
11-15	4,5	1176-1550	17
16-25	5	1551-2025	18
26-45	6	2026-2675	19
46-65	7	2676-3450	20
66-85	8	3451-4350	21
86-125	10	4351-5450	22
126-175	11	5451-6800	23
176-275	12	6801-8500	24
276-425	13	8501-10700	25
426-625	14	> 10700	Follow progression above.

Table 3- Annual Document Fee Table:

DOCUMENT NAME	ANNUAL CERTIFICATE OF USE FEE
EN ISO 9001:2015	500 €
EN ISO 13485:2016	1.000 €
Other system documents	200 €