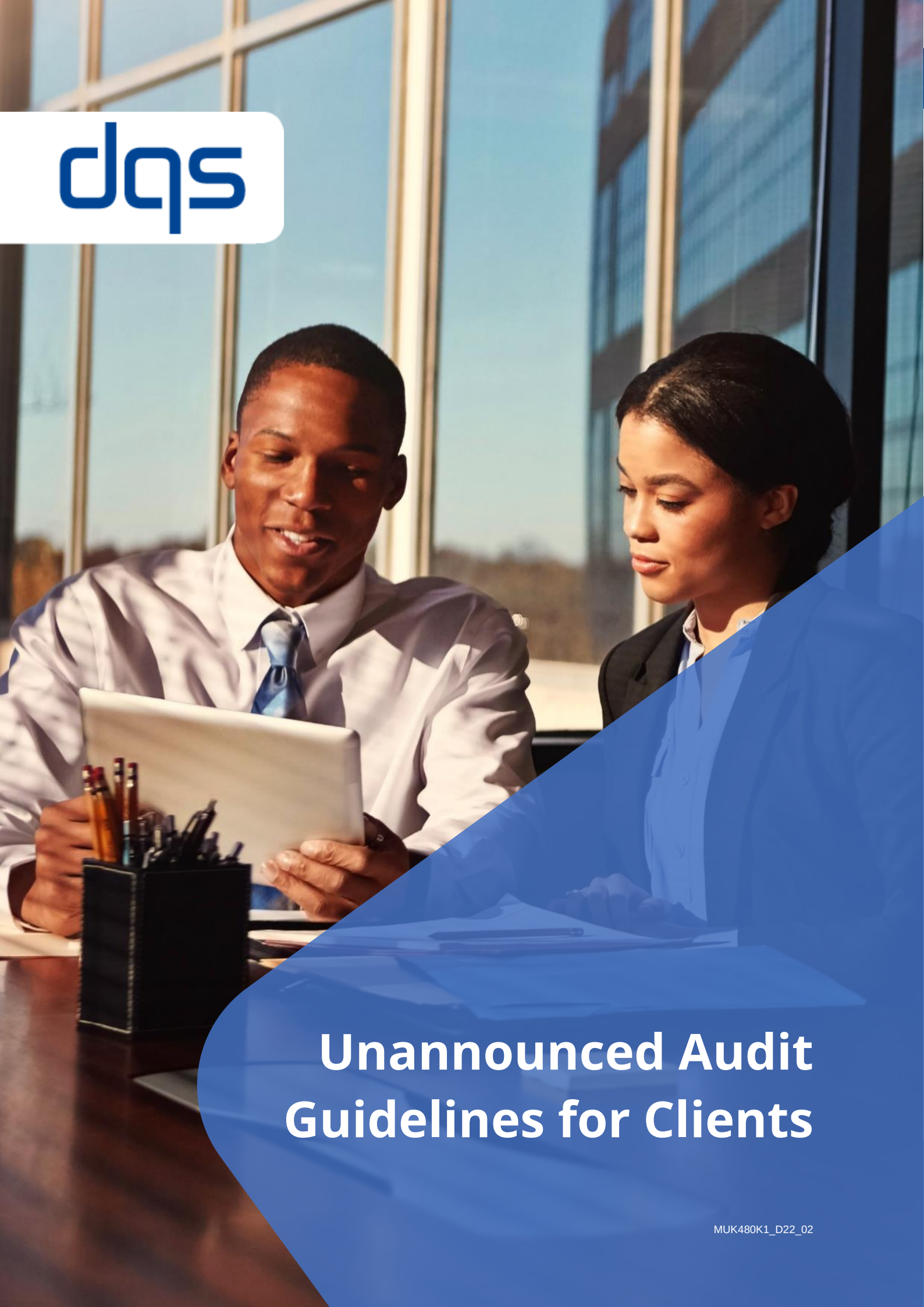

Unannounced Audit Guidelines for Clients

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Introduction

Unannounced audits are part of the conformity assessment activities for your UKCA certification under the UK Medical Devices Regulation 2002(SI 2002 No 618, as amended) (UK MDR). As the name suggest, these audits are performed without prior notification to the audit site. The audits are conducted by at least 2 DQS auditors, the auditors will be on site for at least 1 day, but the audit may last several days. These audits assure the day-to-day compliance of the management system you have implemented and the conformity of the products you produce. However, the unannounced audits do not replace surveillance audit days.

What to expect

When our auditors arrive on site, they will make themselves known to the reception and provide a copy of an audit team letter and identification. You may wish to authenticate the audit by calling our office and independently verify the auditors' identity. The responsibility for authentication lies with the manufacturer, including any delays it may cause. Please note that the authentication should be performed immediately as it is important that we are able to audit the production area soon after we notify you of our arrival. We expect to be able to perform a tour of the production area of our choice within 20 minutes of our arrival.

After the visit to the production site, the auditors will examine the technical documentation of the selected representative product, working through records to ensure that they align with the relevant requirements. The mandatory elements to be audited include the conformity of the selected device with the technical documentation and legal requirements, traceability of critical components and materials, and traceability of the device to the end user. The audit assesses the representative product selected and also includes manufacturing activity ongoing at the time of the visit.

The audit team may request a product, material or component sample for further testing. The testing may be performed on site following your usual processes and witnessed by the audit team, or samples may be requested for independent testing. Testing is only usually required where the Audit Team has reasonable doubts about conformity of the device type(s). The costs related to the acquisition of samples and the testing are borne by the client.

At the end of the audit, the Lead Auditor will present the legal manufacturer named on the certificate with a draft report, including any non-conformities. Dissemination of this information is the responsibility and under the authority of the legal manufacturer. Management of the non-conformities follows our audit process requirements, and your plans need to be submitted to us within 5 working days of the last audit day on site.

In most cases, our clients are prepared for the unannounced visit. They have informed their employees of the requirements and established processes to support this type of audits. This training is an investment because your support in the unannounced visit will keep your costs to the minimum.

The unannounced visits are generally shorter than surveillance visits and they focus on the product and production, whereas surveillance audits focus on the management system.

Sites included

Our unannounced audits are planned to include manufacturing facilities that are critical for product quality. At least one unannounced audit will be conducted in the certification cycle. The site will be chosen by the Regulatory Affairs Manager in the planning stage. In addition, unannounced audits may be conducted at facilities of critical subcontractors or original equipment manufacturers. Your contracts should ensure that these unannounced audits can take place, covering confidentiality and other requirements. The costs of these UNAs are borne by the legal manufacturer and invoiced directly to them.

Sites are considered for unannounced audits no matter where they are located in the world and the delivery of the audit remains the same. In order to ensure that we can obtain the right to access your global sites and sites of your critical manufacturers, we may request an open letter of invitation for visa purposes. If we are unable to visit a site, it cannot be included in your certification.

Products included

All products listed on your certificates are considered in the unannounced audit programme. We group them according to device types, where a device type includes product models that have a common design, construction, parts or assemblies essential to ensure conformity with applicable requirements.

Reporting

We will present our report to the legal manufacturer after the audit. Our report documents the assessment. We aim to provide a final report within 7 days of the closing meeting. We will also provide you with any updates to the plan of the assessment activities to maintain your certification if changes are required.

Findings

Our report will document any findings based on the information we assessed. We will classify findings as minor and major.

Minor findings do not affect the capability of the management system to achieve the intended result, including product conformity, but need to be addressed to ensure the future capability of the system.

Where minor findings are raised in an assessment that leads to certification, our assessor will ask you to provide details of your proposed impact assessment, correction (where applicable), and root cause analysis and corrective action. This information will be part of our package that we send to independent review (see Certification). Where minor findings are raised at surveillance audits, we will usually review them at our next visit or within 12 months of the audit at the latest.

Major findings affect the capability of the management system to achieve the intended result. Examples could be the absence of, or failure to implement and maintain, one or more management system elements. Major findings also include:

- situations that would raise significant doubt that there is effective process control in place.

- situations that would raise significant doubt that products or service will meet specified requirements.
- there are a number of minor findings relating to the same requirement.
- There is an issue that could demonstrate a systematic failure.
- A situation that requires immediate containment.

Major non-conformities will need to be closed before we can issue the certification and we may need to perform additional on-site assessment to verify the effectiveness of the actions you have implemented.

Our assessor will present all findings in the closing meeting of your assessment and ensure that you understand the finding and the next steps.

Certification

The results of the unannounced audit may impact your certification. Where there is reasonable doubt that the conformity assessment requirements are met, either due to the direct audit outcome or progression of the actions to address non-conformities, a recommendation may be made to change your certification. This recommendation may put conditions or restriction on your current certification, or it may lead to suspension or withdrawal of our certification.

You will be kept informed of the progress of your project and any recommendations.

Costs

Individual unannounced audits are not quoted in advance. You may contact your Customer Service Representative for a generic cost estimate for an unannounced audit at your site or the site of a critical supplier.

All costs incurred will be invoiced to the certified manufacturer, including travel and expenses (which are aligned to regular audit tariffs).

The costs of any test samples, their shipping (as applicable) and testing is borne by the manufacturer.

Troubleshooting

In the event of our unannounced audit team being refused entry or being obstructed in the audit process, the Lead Auditor reserves the right to abort the audit. The report is completed as far as possible with a recommendation for suspension, withdrawal, or reduction of scope of the certificate, as appropriate. This also applies where our auditors are not able to audit the selected processes or TD.

We expect that you notify us of any closure of your site and critical supplier sites in the annual update of the **Basic Data Form**. This includes closure of your critical manufacturer and supplier sites. You may also provide additional timely (at least 6 weeks in advance) information regarding closure during the year. If we arrive on site and we cannot access the site because it is closed, or for any other reason that we have not had prior notification of, the audit will be aborted. The invoice for the audit, including travel and accommodation costs, are borne by the manufacturer.

In certain cases, we may arrive for an unannounced audit on a day when your preferred staff members are not available. This situation would not lead to changes in

the audit plans as we expect manufacturing sites to implement policies and processes to

ensure all relevant staff are available at short notice required to deal with unexpected situations, included unannounced audits. This availability includes cover for absences.

For manufacturers with multiple certificates provided by organisations other than DQS, the situation may arise that our unannounced audit is in conflict with another certification audit. In such circumstances, we would continue with the audit, noting the situation in the audit report and taking consideration to any staff shortages.

Our unannounced auditors are able to conduct the full audit in English. Where a translator is required for a site audit, we will arrange for translator to accompany our audit team. We plan the need for translators based on the information you have provided in the **Basic Data Form**. Please ensure that this information is kept up to date.

Closing remarks

Assessments are based on sampling. This means that your previous assessments may not have identified an issue that could be identified in the future. Even where you have a history of compliance, any audit can identify previously undetected and new issues.

Should you have any questions, please do not hesitate to ask us using our enquiries email box dqs-uk@dqs.de

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