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| **MPACE GAP ANALYSIS REQUIREMENTS** |

1. **Introduction**

UKAS has established a project to develop an accreditation scheme in the area of Medical Physics and Clinical Engineering. Any organization wishing to gain accreditation in this area will need to demonstrate compliance against the requirements of BS 70000 “Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence”. The accreditation standard is split into two sections, firstly detailing management system requirements and secondly technical requirements which will be relevant to the specific area of MPACE which an organization is seeking accreditation in. If an organization is looking to cover multiple MPACE areas the majority of management system requirements will be the same and can be managed centrally, however some of the requirements in Section 4 will require consideration for the different areas.

A copy of BS 70000 can be purchased from BSi who own the copy rights for this publication. UKAS does not currently have permission to copy the content of BS 70000 into this gap analysis form therefore applicants will need to fill in this form in conjunction with BS 70000.

1. **Objective**

This document is aimed at providing all potential MPACE applicant with a mechanism to identify gaps between their current documented management system and supporting evidence against the requirements of BS 70000.

1. **UKAS requirements for applicant MPACE organizations**

Please complete this MPACE Gap Analysis form and confirm compliance with each clause. If you are currently compliant please indicate where in your management system the clause is addressed. If your management system is currently non-compliant please detail what actions you plan to take to address the gap and the associated timescale for completion.

BS 70000 was written to cover a wider range of Medical Physics and Clinical Engineering activities. A number of the requirements will not be relevant to the area of <…………..>. Clauses highlighted in orange may not be relevant depending on the structure and setup of specific units.

Please note that there will be clauses which will need to be discussed/investigated further as part of the development of the scheme. At this point in time these clauses have not be highlighted in the gap analysis form. However if you do not feel they are relevant please make comment in the right hand column.

**Annex 1**

**Gap Analysis and Transition Plan**

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| --- | --- |
| **Name of Organisation** | Click here to enter text |
| **Technical Discipline** | Click here to enter text |
| **Date of Submission** | Select a date from the calendar |

**GAP ANALYSIS**

| **SECTION** | **CLAUSE** | **COMPLIANT** | | | **EVIDENCE WHICH SUPPORTS COMPLIANCE STATEMENT**  **(e.g. Reference to Procedure/Clause, Reference Material, Reports, agreements, minutes of meetings)** | **ACTIONSPLANNED TO ADDRESS ANY GAPS**  **(e.g. Update specific Procedure, develop Work Instruction, design/implement quality checks)** |
| --- | --- | --- | --- | --- | --- | --- |
| **YES** | **NO** | **N/A** |
|  |  |  |  |  |  |  |
| **Management Requirements** | 4 |  |  |  |  |  |
| **Organization** | 4.1. |  |  |  |  |  |
|  | 4.1.1 |  |  |  |  |  |
|  | 4.1.2 |  |  |  |  |  |
|  | 4.1.3 |  |  |  |  |  |
|  | 4.1.4 |  |  |  |  |  |
|  | 4.1.5 |  |  |  |  |  |
|  | 4.1.6 |  |  |  |  |  |
|  | 4.1.7 |  |  |  |  |  |
|  | 4.1.8 |  |  |  |  |  |
|  | 4.1.9 |  |  |  |  |  |
| Quality Management System | 4.2 |  |  |  |  |  |
|  | 4.2.1 |  |  |  |  |  |
|  | 4.2.2 |  |  |  |  |  |
| Governance and Risk Management | 4.3 |  |  |  |  |  |
| Governance Policies | 4.3.1 |  |  |  |  |  |
|  | 4.3.2 |  |  |  |  |  |
|  | 4.3.3 |  |  |  |  |  |
|  | 4.3.4 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Planning to achieve Management Objectives | 4.4 |  |  |  |  |  |
|  | 4.4.1 |  |  |  |  |  |
|  | 4.4.2 |  |  |  |  |  |
|  | 4.4.3 |  |  |  |  |  |
| Service Delivery | 4.5 |  |  |  |  |  |
|  | 4.5.1 |  |  |  |  |  |
|  | 4.5.2 |  |  |  |  |  |
|  | 4.5.3 |  |  |  |  |  |
|  | 4.5.4 |  |  |  |  |  |
|  | 4.5.5 |  |  |  |  |  |
| Management Change | 4.6 |  |  |  |  |  |
|  | 4.6.1 |  |  |  |  |  |
|  | 4.6.2 |  |  |  |  |  |
|  | 4.6.3 |  |  |  |  |  |
| Outsourcing | 4.7 |  |  |  |  |  |
|  | 4.7.1 |  |  |  |  |  |
|  | 4.7.2 |  |  |  |  |  |
|  | 4.7.3 |  |  |  |  |  |
|  | 4.7.4 |  |  |  |  |  |
|  | 4.7.5 |  |  |  |  |  |
|  | 4.7.6 |  |  |  |  |  |
| Management of Suppliers | 4.8 |  |  |  |  |  |
|  | 4.8.1 |  |  |  |  |  |
|  | 4.8.2 |  |  |  |  |  |
|  | 4.8.3 |  |  |  |  |  |
| Document Control | 4.9 |  |  |  |  |  |
| General | 4.9.1 |  |  |  |  |  |
|  | 4.9.1.1 |  |  |  |  |  |
|  | 4.9.1.2 |  |  |  |  |  |
|  | 4.9.1.3 |  |  |  |  |  |
|  | 4.9.1.4 |  |  |  |  |  |
| Document approval and issue | 4.9.2 |  |  |  |  |  |
|  | 4.9.2 |  |  |  |  |  |
| Document changes | 4.9.3 |  |  |  |  |  |
|  | 4.9.3.1 |  |  |  |  |  |
|  | 4.9.3.2 |  |  |  |  |  |
| Control of nonconforming work | 4.10 |  |  |  |  |  |
|  | 4.10.1 |  |  |  |  |  |
|  | 4.10.2 |  |  |  |  |  |
|  | 4.10.3 |  |  |  |  |  |
| Control of unexpected findings | 4.11 |  |  |  |  |  |
|  | 4.11.1 |  |  |  |  |  |
|  | 4.11.2 |  |  |  |  |  |
| Service Improvement | 4.12 |  |  |  |  |  |
|  | 4.12.1 |  |  |  |  |  |
|  | 4.12.2 |  |  |  |  |  |
| Quality indicators | 4.13 |  |  |  |  |  |
|  | 4.13.1 |  |  |  |  |  |
|  | 4.13.2 |  |  |  |  |  |
|  | 4.13.3 |  |  |  |  |  |
|  | 4.13.4 |  |  |  |  |  |
| Staff engagement | 4.14 |  |  |  |  |  |
|  | 4.14 |  |  |  |  |  |
| Corrective action | 4.15 |  |  |  |  |  |
|  | 4.15.1 |  |  |  |  |  |
|  | 4.15.2 |  |  |  |  |  |
| Preventive Action | 4.16 |  |  |  |  |  |
|  | 4.16.1 |  |  |  |  |  |
|  | 4.16.2 |  |  |  |  |  |
| Control of information assets | 4.17 |  |  |  |  |  |
| General | 4.17.1 |  |  |  |  |  |
|  | 4.17.1.1 |  |  |  |  |  |
|  | 4.17.1.2 |  |  |  |  |  |
|  | 4.17.1.3 |  |  |  |  |  |
|  | 4.17.1.4 |  |  |  |  |  |
|  | 4.17.1.5 |  |  |  |  |  |
|  | 4.17.1.6 |  |  |  |  |  |
| Technical Records | 4.17.2 |  |  |  |  |  |
|  | 4.17.2.1 |  |  |  |  |  |
|  | 4.17.2.2 |  |  |  |  |  |
|  | 4.17.2.3 |  |  |  |  |  |
|  | 4.17.2.4 |  |  |  |  |  |
| Internal Audits | 4.18 |  |  |  |  |  |
|  | 4.18.1 |  |  |  |  |  |
|  | 4.18.2 |  |  |  |  |  |
|  | 4.18.3 |  |  |  |  |  |
|  | 4.18.4 |  |  |  |  |  |
|  | 4.18.5 |  |  |  |  |  |
|  | 4.18.6 |  |  |  |  |  |
|  | 4.18.7 |  |  |  |  |  |
|  | 4.18.8 |  |  |  |  |  |
| Management Review | 4.19 |  |  |  |  |  |
|  | 4.19.1 |  |  |  |  |  |
|  | 4.19.2 |  |  |  |  |  |
|  | 4.19.3 |  |  |  |  |  |
| Assuring Quality in Research and Development Activities | 4.20 |  |  |  |  |  |
| Implementation of Innovative practice | 4.20.1 |  |  |  |  |  |
|  | 4.20.1 |  |  |  |  |  |
| Engagement in, and organization and governance of, research and development | 4.20.2 |  |  |  |  | *<Do not need to complete if Department does not undertake any Research and Development activities.>* |
|  | **4.20.2.1** |  |  |  |  |  |
|  | **4.20.2.2** |  |  |  |  |  |
|  | **4.20.2.3** |  |  |  |  |  |
|  | **4.20.2.4** |  |  |  |  |  |
|  | **4.20.2.5** |  |  |  |  |  |
|  | **4.20.2.6** |  |  |  |  |  |
|  | **4.20.2.7** |  |  |  |  |  |
| Assuring quality in education and training activities | 4.21 |  |  |  |  | *< Do not need to complete if Department does not participate in any education training package>*  *Training of own staff to undertake activities will be assessed via this section and details in 5.2>* |
| Organization and governance of education and training activities | 4.21.1 |  |  |  |  |  |
|  | **4.21.1.1** |  |  |  |  |  |
|  | **4.21.1.2** |  |  |  |  |  |
|  | **4.21.1.3** |  |  |  |  |  |
|  | **4.21.1.4** |  |  |  |  |  |
|  | **4.21.1.5** |  |  |  |  |  |
|  | **4.21.1.6** |  |  |  |  |  |
|  | **4.21.1.7** |  |  |  |  |  |
|  | **4.21.1.8** |  |  |  |  |  |
| Access to education and training | **4.21.2** |  |  |  |  |  |
|  | **4.21.2.1** |  |  |  |  |  |
|  | **4.21.2.2** |  |  |  |  |  |
|  | **4.21.2.3** |  |  |  |  |  |
|  | **4.21.2.4** |  |  |  |  |  |
| Quality Standards for education and training activities | **4.21.3** |  |  |  |  |  |
|  | **4.21.3.1** |  |  |  |  |  |
|  | **4.21.3.2** |  |  |  |  |  |
| Supervision and progression of trainees | 4.2.1.4 |  |  |  |  |  |
|  | **4.21.4.1** |  |  |  |  |  |
|  | **4.21.4.2** |  |  |  |  |  |
|  | **4.21.4.3** |  |  |  |  |  |
| Partnership in education and training | 4.21.5 |  |  |  |  |  |
|  | **4.21.5.1** |  |  |  |  |  |
|  | **4.21.5.2** |  |  |  |  |  |
| Training and workforce planning | 4.21.6 |  |  |  |  |  |
|  | **4.21.6.1** |  |  |  |  |  |
|  | **4.21.6.2** |  |  |  |  |  |
| Technical Requirements | 5 |  |  |  |  |  |
| General | 5.1 |  |  |  |  |  |
|  | **5.1.1** |  |  | N/A |  | *<No documentation required but organization needs to ensure that these aspects are covered.>* |
|  | 5.1.2 |  |  |  |  |  |
| Personnel | 5.2 |  |  |  |  |  |
|  | 5.2.1 |  |  |  |  |  |
|  | 5.2.2 |  |  |  |  |  |
|  | 5.2.3 |  |  |  |  |  |
|  | 5.2.4 |  |  |  |  |  |
|  | 5.2.5 |  |  |  |  |  |
| Facilities and environmental conditions | 5.3 |  |  |  |  |  |
|  | 5.3.1 |  |  |  |  |  |
|  | 5.3.2 |  |  |  |  |  |
|  | 5.3.3 |  |  |  |  |  |
|  | 5.3.4 |  |  |  |  |  |
|  | 5.3.5 |  |  |  |  |  |
|  | 5.3.6 |  |  |  |  |  |
|  | 5.3.7 |  |  |  |  |  |
|  | 5.3.8 |  |  |  |  |  |
|  | 5.3.9 |  |  |  |  |  |
| Operation method/procedures and validation | 5.4 |  |  |  |  |  |
| General | 5.4.1 |  |  |  |  |  |
|  | 5.4.1.1 |  |  |  |  |  |
|  | 5.4.1.2 |  |  |  |  |  |
| Selection of methods and procedures | 5.4.2 |  |  |  |  |  |
|  | 5.4.2.1 |  |  |  |  |  |
|  | 5.4.2.2 |  |  |  |  |  |
|  | 5.4.2.3 |  |  |  |  |  |
|  | 5.4.2.4 |  |  |  |  |  |
|  | 5.4.2.5 |  |  |  |  |  |
| Service-implemented methods and procedures | 5.4.3 |  |  |  |  |  |
|  | 5.4.3.1 |  |  |  |  |  |
|  | 5.4.3.2 |  |  |  |  |  |
| Non-standard methods and procedures | 5.4.4 |  |  |  |  |  |
|  | 5.4.4 |  |  |  |  |  |
| Validation of methods and procedures | 5.4.5 |  |  |  |  | <this is an area covers involves detailing the evidence is there to demonstrate methods are fit for purpose and that the required level of accuracy which can be achieved. In addition, that the results are repeatable within the relevant unit> |
|  | 5.4.5.1 |  |  |  |  |  |
|  | 5.4.5.2 |  |  |  |  |  |
|  | 5.4.5.3 |  |  |  |  |  |
|  | 5.4.5.4 |  |  |  |  |  |
| Estimation of uncertainty of measurement | 5.4.6 |  |  |  |  | < if uncertainty can not be quantified then source of uncertainty must be identified and details of how these source of uncertainty are mitigated or minimized.> |
|  | 5.4.6.1 |  |  |  |  |  |
|  | 5.4.6.2 |  |  |  |  |  |
| Measurement uncertainty of measurement quantity values | 5.4.7 |  |  |  |  |  |
|  | 5.4.7.1 |  |  |  |  |  |
|  | 5.4.7.2 |  |  |  |  |  |
|  | 5.4.7.3 |  |  |  |  |  |
| Reference intervals and clinical action thresholds | 5.4.8 |  |  |  |  |  |
|  | 5.4.8.1 |  |  |  |  |  |
|  | 5.4.8.2 |  |  |  |  |  |
|  | 5.4.8.3 |  |  |  |  |  |
| Control of Data | 5.4.9 |  |  |  |  |  |
|  | 5.4.9.1 |  |  |  |  |  |
|  | 5.4.9.2 |  |  |  |  |  |
| Verification of production or intervention procedures | 5.4.10 |  |  |  |  | <This section is assessed in conjunction with 5.4.5 and is relevant when verifying process provided by a 3rd party source such medical device manufacturers > |
|  | 5.4.10.1 |  |  |  |  |  |
|  | 5.4.10.2 |  |  |  |  |  |
|  | 5.4.10.3 |  |  |  |  |  |
|  | 5.4.10.4 |  |  |  |  |  |
|  | 5.4.10.5 |  |  |  |  |  |
| Equipment | 5.5 |  |  |  |  |  |
| Medical device management | 5.5.1 |  |  |  |  | < note that this section relates to the equipment used within the department not the medical device which might be examined> |
|  | 5.51.1 |  |  |  |  |  |
|  | 5.5.1.2 |  |  |  |  |  |
|  | 5.5.1.3 |  |  |  |  |  |
|  | 5.5.1.4 |  |  |  |  |  |
|  | 5.5.1.5 |  |  |  |  |  |
|  | 5.5.1.6 |  |  |  |  |  |
|  | 5.5.1.7 |  |  |  |  |  |
|  | 5.5.1.8 |  |  |  |  |  |
|  | 5.5.1.9 |  |  |  |  |  |
|  | 5.5.1.10 |  |  |  |  |  |
|  | 5.5.1.11 |  |  |  |  |  |
|  | 5.5.1.12 |  |  |  |  |  |
|  | 5.5.1.13 |  |  |  |  |  |
|  | 5.5.1.14 |  |  |  |  |  |
|  | 5.5.1.15 |  |  |  |  |  |
|  | 5.5.1.16 |  |  |  |  |  |
|  | 5.5.1.17 |  |  |  |  |  |
|  | 5.5.1.18 |  |  |  |  |  |
|  | 5.5.1.19 |  |  |  |  |  |
| Measurement Traceability | 5.6 |  |  |  |  |  |
| General | 5.6.1 |  |  |  |  |  |
| Metrological confirmation | 5.6.2 |  |  |  |  |  |
|  | 5.6.2.1 |  |  |  |  |  |
|  | 5.6.2.2 |  |  |  |  |  |
|  | 5.6.2.3 |  |  |  |  |  |
| Reference Standards and Reference Materials | 5.6.3 |  |  |  |  |  |
| Reference Standards | 5.6.3.1 |  |  |  |  |  |
|  | 5.6.3.1 |  |  |  |  |  |
| Reference equipment and materials | 5.6.3.2 |  |  |  |  |  |
|  | 5.6.3.2 |  |  |  |  |  |
| Intermediate checks | 5.6.3.3 |  |  |  |  |  |
|  | 5.6.3.3 |  |  |  |  |  |
| Transport and storage | 5.6.3.4 |  |  |  |  |  |
|  | 5.6.3.4 |  |  |  |  |  |
| Sampling | 5.7 |  |  |  |  | May be relevant to non-diagnostic imaging and sampling of blood. |
|  | 5.7.1 |  |  |  |  |  |
|  | 5.7.2 |  |  |  |  |  |
|  | 5.7.3 |  |  |  |  |  |
| Handling of production, investigation … metrological confirmation items | 5.8 |  |  |  |  | <There maybe physical samples or digital files transferred, or medical device submitted to department for PPM> |
|  | 5.8.1 |  |  |  |  |  |
|  | 5.8.2 |  |  |  |  |  |
|  | 5.8.3 |  |  |  |  |  |
|  | 5.8.4 |  |  |  |  |  |
|  | 5.8.5 |  |  |  |  |  |
|  | 5.8.6 |  |  |  |  |  |
|  | 5.8.7 |  |  |  |  |  |
| Controlling the quality of healthcare scientific service outputs | 5.9 |  |  |  |  |  |
|  | 5.9.1 |  |  |  |  |  |
|  | 5.9.2 |  |  |  |  |  |
| Service Processes | 5.10 |  |  |  |  |  |
| General | 5.10.1 |  |  |  |  |  |
|  | 5.10.1.1 |  |  |  |  |  |
|  | 5.10.1.2 |  |  |  |  |  |
| Information for patients and service users | 5.10.2 |  |  |  |  | <information for patients may not be responsibility of the department and therefore not relevant, however information for service users is relevant> |
|  | 5.10.2.1 |  |  |  |  |  |
|  | 5.10.2.2 |  |  |  |  |  |
| Service request form information | 5.10.3 |  |  |  |  |  |
|  | 5.10.3.1 |  |  |  |  |  |
|  | 5.10.3.2 |  |  |  |  |  |
|  | 5.10.3.3 |  |  |  |  |  |
| Transportation | 5.10.4 |  |  |  |  | <potentially not relevant> |
|  | 5.10.4 |  |  |  |  |  |
| Equipment, product, patient, sample or data reception | 5.10.5 |  |  |  |  |  |
|  | 5.10.5 |  |  |  |  |  |
| Service output management | 5.11 |  |  |  |  |  |
| Review of results | 5.11.1 |  |  |  |  |  |
|  | 5.11.1.1 |  |  |  |  |  |
|  | 5.11.1.2 |  |  |  |  |  |
| Control of unexpected findings | 5.11.2 |  |  |  |  |  |
| Storage, retention and disposal of equipment, chemical ….. clinical waste and samples | 5.11.3 |  |  |  |  |  |
|  | 5.11.3.1 |  |  |  |  |  |
|  | 5.11.3.2 |  |  |  |  |  |
|  | 5.11.3.3 |  |  |  |  |  |
| Surveillance | 5.12 |  |  |  |  | <Only relevant for production/maintenance of medical devices> |
|  | 5.12 |  |  |  |  |  |
| Reporting the Results | 5.13 |  |  |  |  | <Need to consider what the output from the Service is, report, plans, certificate, records updated on system Relevant sections need to be completed (5.13.2-5.13.9> |
| General | 5.13.1 |  |  |  |  |  |
|  | 5.13.1.1 |  |  |  |  |  |
|  | 5.13.1.2 |  |  |  |  |  |
|  | 5.13.1.3 |  |  |  |  |  |
| Diagnostic or therapeutic intervention, repair, test reports and metrological confirmation certificates | 5.13.2 |  |  |  |  |  |
|  | 5.13.2.1 |  |  |  |  |  |
|  | 5.13.2.2 |  |  |  |  |  |
| Diagnostic or therapeutic intervention, repair and test reports | 5.13.3 |  |  |  |  |  |
|  | 5.13.3 |  |  |  |  |  |
| Production and metrological confirmation certificates | 5.13.4 |  |  |  |  |  |
|  | 5.13.4.1 |  |  |  |  |  |
|  | 5.13.4.2 |  |  |  |  |  |
|  | 5.13.4.3 |  |  |  |  |  |
|  | 5.13.4.4 |  |  |  |  |  |
|  | 5.13.4.6 |  |  |  |  |  |
| Professional advice, opinions and interpretations | 5.13.5 |  |  |  |  |  |
| Testing and metrological confirmation results obtained from outsourcing contractors | 5.13.6 |  |  |  |  |  |
|  | 5.13.6.1 |  |  |  |  |  |
|  | 5.13.6.2 |  |  |  |  |  |
| Electronic transmission of results | 5.13.7 |  |  |  |  |  |
| Format of reports and certificates | 5.13.8 |  |  |  |  |  |
|  | 5.13.8.1 |  |  |  |  |  |
| Amendments to production, diagnostics or therapeutic intervention, repair, test reports or certificates | 5.13.9 |  |  |  |  |  |
|  | 5.13.9.1 |  |  |  |  |  |
|  | 513.9.2 |  |  |  |  |  |