

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
1.	IPEM			General	<p>IPEM is supportive of developing robust and workable accreditation standards that support and underpin effective medical physics and clinical engineering services. Institute members have contributed to the development of the draft for comment, with comments below arising from wider consultation with the membership</p> <p>IPEM's members have also commented individually, both on the standards structure, content and readability. These comments therefore focus more on the significant issues that IPEM would like to see further considered as part of the drafting process</p> <p>IPEM notes (and supports) UKAS's, the United Kingdom Accreditation Service description of accreditation.</p> <p>"Accreditation is the formal recognition that an organisation is competent to perform specific processes, activities, or tasks (which are detailed in a scope of accreditation) in a reliable credible and accurate manner"</p> <p>IPEM members are already making considerable use of certification standards such as ISO 9001 and ISO</p>	<p>Clarify the scope of accreditation, together with relationships of existing certification standards and whether specific scopes are warranted for the sub-specialisms within the profession</p>		

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
					13485 to give confidence in their service provision.			
2.	IPEM	Positioning Statement			<p>General comments received from members have been regarding the interaction of this standard with existing quality management schemes based on ISO 9001, as well as existing accreditation standards. Whilst recognising that it may be difficult to immediately clarify the final accreditation landscape it was felt that it would be helpful if the positioning statement attempted to address more specifically and practically the relationship between quality and accreditation standards. Will, for instance accreditation to BS 70000, actually confer certification to ISO 9001?</p> <p>Working relationships, for instance, between IQulPS, ICEPSS and Community Equipment Code of Practise Scheme need further clarification</p>	<p>Review the positioning statement</p> <p>Consider an informative rationale to explore these factors in more detail</p>		
3.	IPEM			General	<p>Members have commented on the fact that the structure of the document feels very different from other management system standards.</p> <p>ISO 9001:2015 is being considered by departments who have registration and a request has been made to suggest more</p>	<p>Consider improved alignment and terminology with ISO 9001:2015</p> <p>Consider renaming of the standard to</p>		

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
					alignment between terminology This specifically applies to the title of BS 70000 which should perhaps read products and services	cover products and services		
4.	IPEM			General	Whilst recognising this is a standard describing emerging service accreditation concepts there has been a concern expressed by members of the large number of mandatory requirements, expressed throughout the standard via the usage of the auxiliary verb "shall". Very few of the requirements have an accompanying "test methodology" hence compliance appears to be open to interpretation by the assessor. As a Professional body IPEM is keen to ensure coherent assessment standards evolve	Consider the number of mandatory requirements and consider describing how compliance will be achieved.		
5.	IPEM	Positioning Statement		General	The positioning statement includes the phrase..... "focusing on the scientific aspects of service delivery" IPEM feedback has suggested that this should be more comprehensive	Extend to read scientific, technical, managerial and leadership aspects		
6.	IPEM	Annexes	2-5	General	Whilst these informative annexes provide useful scene setting on the range of medical physics and clinical engineering specialisms there is concern that the	Review the appendices to reflect the totality of the medical physics and clinical engineering workforce		

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
					description of the workforce is limited to Clinical Scientists. IPEM would like to see more comprehensive reference to the workforce across the career framework			
7.	IPEM	Bibliography			The bibliography does not seem exhaustive and many standards that are routinely used in medical physics and clinical engineering services are not referenced. IPEM recommend that there is fundamental review and re-discussion of the relevant standards reference in the document	Review standards currently used in practice within medical physics and clinical engineering services		
8.	IPEM	Scope			The standard is not felt to describe an ethical framework as currently structured	Delete ethical		
9.	IPEM	Normative references			The normative references appear to exclude key standards already used by medical Physics and clinical engineering services. Such as..... BS EN ISO 13485, BS EN ISO 14971 are relevant to the maintenance, design and manufacture of medical equipment and devices.	IPEM's view would be to reference and cite existing standards that could be used to underpin elements of BS 70000		
10.	IPEM	Introduction			The standard now refers to Design and Manufacture within the Introduction, and also production within the Technical Requirements. This is very much welcomed and a key point that was raised with ICEPSS. However, compliance with BS7000 and hence ISO9001 will not provide compliance with ISO13485 in	Reference should be made to the adoption of ISO14791 risk management standard for medical devices, and/or additional certification to the ISO13485 for the appropriate design and manufacture of		

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
					respect of the design and manufacture of all medical devices, including software as a medical device. Further, there are questions around will compliance with this standard demonstrate or confer certification to ISO9001 for design, and accreditation to ISO 17025/15189 as a testing laboratory.	medical devices		
11.	IPEM	Appendix		Tech	Not all of the Clinical Engineering sub disciplines are identified. In particular Device design, which now includes clinical computing. Suggest -	that Clinical Instrumentation definition is changed to "Medical Device /Equipment Design - Engineering scientists and technologists are involved in the design and development of new instruments and software, as well as their clinical use and routine preventive and corrective maintenance		
12.	IPEM	4		Tech	Clarification is required as to whether the reference is to distinct policies for services or whether reliance on organisational wide policies is acceptable	Clarify		
13.	IPEM	5.4.4		Tech	Whilst the spirit of the non-standard methods approach is understandable, there may be occasions where immediate methods are developed to undertake device repairs or measurements to ensure ongoing patient treatment	Ensure that flexibility to ensure service provision, whilst exerting the appropriate controls		
14.								
15.								

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
16.								
17.								
18.								
19.								
20.								
21.								
22.								
23.								
24.								
25.								
26.								
27.								
28.								
29.								
30.								
31.								
32.								
33.								
34.								
35.								
36.								

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
37.								
38.								
39.								
40.								
41.								
42.								
43.								
44.								
45.								
46.								
47.								
48.								
49.								
50.								
51.								
52.								
53.								
54.								
55.								
56.								
57.								

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
58.								
59.								
60.								
61.								
62.								
63.								
64.								
65.								
66.								
67.								
68.								
69.								
70.								
71.								
72.								
73.								
74.								
75.								
76.								
77.								
78.								

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
79.								
80.								
81.								
82.								
83.								
84.								
85.								
86.								
87.								
88.								
89.								
90.								
91.								
92.								
93.								
94.								
95.								
96.								
97.								
98.								
99.								

No	Comment submitted by	Clause./ Subclause/ Annex	Para/Fig/ Table/Note	Type of comment	Comment (justification for change)	Proposed change	Editorial comments (NAME)	Committee decision
100.								
101.								
102.								
103.								
104.								
105.								
106.								