

## JCAHO CLINICAL ENGINEERING STANDARDS STUDY GROUP

April 12, 2004

Dear Members of the JCAHO Committee on Healthcare Safety:

A Study Group composed of the six persons listed on Attachment A was formed early this year to study the new (2004) Joint Commission standards for the management of medical equipment in hospitals. We wish to report our conclusions and recommendations.

We applaud the changes in survey methodology and the continued efforts to assist healthcare organizations in achieving excellence through continuous improvement. The new Shared Visions-New Pathways accreditation process is definitely a major improvement over the prior process. The reduction of the number of standards and clearer specifications of the Elements of Performance (EP) are well appreciated.

As we studied and discussed the implementation challenges, we became aware of issues related to specific EPs in EC.6.10 and EC.6.20. These EPs have generated a great deal of discussion among the clinical engineering professionals who manage medical equipment planning, acquisition and maintenance and who are responsible for critical components of the patient safety program related to medical equipment.

After considerable discussions and iterative draft reviews, we produced some recommended improvements for EPs 3 and 4 of EC.6.10 and EC.6.20 that we respectfully submit to this Committee for consideration.

Although some of the members of this Study Group are probably known to this Committee, we would like to mention that we collectively have over 150 years of combined work experience in the field of clinical engineering. While some of us are responsible for a single hospital system, others cover or provide expertise to hundreds of hospitals. Together, we have published books, book chapters, and numerous articles in peer-reviewed journals and have made countless presentations in professional events in this and other countries. Collectively, we oversee the management of over 500,000 pieces of medical equipment that is worth more than \$5 billion.


Our goal in developing the attached recommendations is to help the Joint Commission improve the medical equipment standards using the knowledge and experience accumulated by the clinical engineering community, including healthcare organizations, independent service organizations, professional associations, and academia. While developing our recommendations, we tried to ensure that the medical equipment standards have the following characteristics:

1. Must effectively help improve patient safety, enhance efficacy, and increase availability and reliability
2. Can be implemented “honestly,” i.e., without manipulations and adjustments
3. Simple and easy to understand, with little or no need of consultants or training courses
4. Flexible, allowing adaptation to the unique characteristics of each organization

Attached please find our recommended improvements. To help you visualize them, we have reproduced the original EPs on the left-most column and shown the recommended wording in the middle column. In the right column, we tried to explain the reason(s) we believe our recommendations will help improve the respective EP.

Thank you for your attention to this matter. We look forward to hearing from you. Please address all correspondence to Binseng Wang but feel free to contact any one of us to discuss or ask for clarification.

Very truly yours,



Binseng Wang, Sc.D., CCE, for the  
JCAHO Clinical Engineering Standards Study Group

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Attachments: - Attachment A: JCAHO Clinical Engineering Standards Study Group Members  
- Attachment B: Suggested Improvements to Equipment Management Standards.

Attachment A

JCAHO CLINICAL ENGINEERING STANDARDS STUDY GROUP MEMBERS

(in alphabetic order)

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ATTACHMENT B

SUGGESTED IMPROVEMENTS TO EQUIPMENT MANAGEMENT STANDARDS

Original JCAHO Text		Suggested Improvements		Rationale
Element of Performance	Scoring	Element of Performance	Scoring	
<p>EC.6.10.3 The organization establishes and uses risk criteria for identifying, evaluating, and creating an inventory of equipment to be included in the medical management plan before the equipment is used. These criteria address the following:</p> <ul style="list-style-type: none"> <li>• Equipment function (diagnosis, care, treatment, and monitoring)</li> <li>• Physical risks associated with use</li> <li>• Equipment incident history</li> </ul> <p><i>Note: The organization may choose not to use risk criteria to limit the types of equipment to be included in the medical equipment management plan, but rather include all medical equipment.</i></p>	Category B	<p>EC.6.10.3 The organization establishes and uses <b>risk</b> criteria for identifying, evaluating, and creating an inventory of equipment to be included in the medical <b>equipment</b> management plan before the equipment is used. <b>The inventory may include all medical equipment or use</b> criteria <b>such as</b> the following:</p> <ul style="list-style-type: none"> <li>• Equipment <b>function (diagnosis, care, treatment, and monitoring's role and importance within the organization's mission (i.e., how critical it is for patient care))</b></li> <li>• <b>The severity, frequency and detectability of</b> physical risks associated with use</li> <li>• <b>Reliability</b></li> <li>• <b>Availability of equipment and of spares or backup</b></li> <li>• Equipment incident, <b>hazard notice and recall</b> history</li> <li>• <b>Inspection and/or preventive maintenance needs</b></li> </ul> <p><i>Note: The organization may <b>choose not to use risk criteria to limit the types of equipment to be included in the medical equipment management plan, but rather include all medical equipment use failure modes and effects analysis – FMEA to establish the inventory.</b></i></p>	Category B	<p>In addition to risk, our experience has shown that several other criteria should also be considered. Also, each organization should be given the flexibility of selecting the appropriate criteria to fit its unique characteristics. The inventory may include all equipment as indicated in the original Note.</p> <p>FMEA, a widely adopted method for measuring risks, is a good tool for determining which equipment to include in the inventory.</p>
<p>EC.6.10.4 The organization identifies appropriate strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory.</p> <p><i>Note: Organizations may use different strategies as appropriate. For example, strategies such as predictive maintenance, interval-based inspections, corrective maintenance, or metered maintenance may be selected to ensure reliable performance.</i></p>	Category B	<p>EC.6.10.4 The organization identifies appropriate <b>inspection and maintenance</b> strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory, <b>and defines criteria for measuring the performance of the inspection and maintenance program.</b></p> <p><i>Note: Organizations may use different strategies <b>for different items</b> as appropriate. For example, strategies such as predictive maintenance, interval-based inspections, <b>statistical sampling</b>, corrective maintenance, or metered maintenance may be selected</i></p>	Category B	<p>Allowing each organization to define its own criteria for performance measurement will provide flexibility to focus clinical engineering attention on equipment that is most critical for achieving the organization's mission.</p>

Original JCAHO Text		Suggested Improvements		Rationale
		<i>to ensure reliable performance. <u>Organizations may use different performance measurements for the inspection and maintenance of different groups of equipment.</u></i>		

Original JCAHO Text		Suggested Improvements		Rationale
Element of Performance	Scoring	Element of Performance	Scoring	
EC.6.20.3 The organization documents maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see EC.6.10).	Category A	EC.6.20.3 <del>The organization documents maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see EC.6.10).</del> <u>Not applicable</u>	NA	We believe there is no need to segregate life-support equipment from the rest, as life support is only one of the inclusion criteria listed in 6.10.3. EP 4 covers both life-support and non-life-support equipment.
EC.6.20.4 The organization documents maintenance of non-life support equipment on the inventory that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see EC.6.10).	Category C	EC.6.20.4 The organization documents <u>inspection and maintenance of</u> <del>non-life support</del> equipment on the inventory that is consistent with <u>the</u> maintenance strategies <del>to minimize clinical and physical risks and the inspection and maintenance performance measurement criteria</del> identified in the equipment management plan (see EC.6.10).	Category <del>C</del> <u>B</u>	The suggested change of Category C scoring to Category B is to reflect the changes recommended in EP 4 of EC.6.20.