CMBES/SCGB

POSITION STATEMENT

Medical Device Inspection Due Labels

Definition

An inspection due label is a sticker that is affixed to a medical device to indicate when the next Preventative Maintenance work is to be completed.

Alternate label descriptions: PM due, due for inspection, record of inspection, inspection stickers, inspection label and service inspection due. For the purpose of this document, inspection due labels will be used to represent all terms.

Scope

This document is intended to provide guidance on affixing inspection due labels to medical equipment that is an asset of the hospital and the responsibility of the in-house biomedical engineering (BME) or clinical engineering department. Although it has not been written from the perspective of vendors or contracted maintenance services, they may find value in the discussion and position taken by the CMBES. Non-hospital service support organizations should abide by their own corporate policies and guidelines regarding medical device inspection due labels.

The issue addressed herein should not be confused with the practice of affixing standard asset labels (i.e. equipment control number) to hospital owned equipment nor should its purpose be confused with certification compliance labels or special inspection labels provided by electrical certification bodies (e.g. CSA or Intertek) for medical equipment. In addition, this document is not intended to cover inspection labels for patient-owned medical equipment that enters the hospital with a patient.

Background

Preventive maintenance (PM) of medical equipment is one of the fundamental services provided by in-house BME departments. Historically, medical device inspection due labels were affixed to medical equipment as a means to alert clinicians and allied health staff when preventive maintenance was due on a particular device.

Guidance literature on this topic is limited except for a few opinion articles. This CMBES Position Statement will discuss the historical reasons for this practice, their relevance with current practice and recommend a formal position statement for BME departments in Canada.

Current Situation

Inertia – The majority of BME departments continue to affix medical device inspection due labels to medical equipment for which they are responsible because that is what has always been done. It is known that the practice of affixing inspection due labels varies across facilities, organizations, provincial and national boundaries. Generally, changing course on affixing inspection due labels requires planning, education and resources that many BME departments are either unable or unwilling to invest, and the status quo persists. Others may fear changing inspection due labels will have implications for Accreditation Canada results, confuse clinicians or diminish accountability for service.

Identification of PM Compliance - Conventional wisdom suggests that the use of labels provides a clinician with immediate-on-device indication of preventive maintenance compliance. This notion hinges on the assumption that clinicians are aware of the label, and, if they see an overdue

inspection, that they know the device should be sent to BME for service [1]. PM compliance is the sole responsibility of BME and it is unreasonable to expect clinicians to perform this task [3].

BME departments no longer use paper based asset management systems but rather a computerized maintenance management system (CMMS). The use of an electronic database to both schedule and record PM work on a particular asset also offers the ability to forecast and plan for upcoming PMs and identify overdue PMs. It is the responsibility of the BME department to manage the PM program, and as such, generate periodic status reports on PM compliance and actively find their own equipment to PM. Relying on clinicians to send overdue equipment for inspection is an unreasonable expectation.

Real-time locating system (RTLS) – These systems are expensive, and have not achieved critical mass in Canadian institutions. For the few hospitals that have implemented an RTLS system, locating equipment that is due for PM is easier.

Time – Although the additional time required each PM to remove old labels and add new labels is marginal, when repeated thousands of times per year the time expended adds up.

Label Information – Inspection due labels should not be relied on for current PM information because over time, they can become illegible or removed [2]. It is generally agreed, that it is the future calendar date that is recorded on the label for identification. Label information is not standardized, leaving hospitals to determine important information to include on the label. Alternatively, some hospital, use differentiating coloured inspection due labels to indicate when the device was last inspected (e.g. green one year, yellow the next, etc.), which helps indicate at-a-glance equipment due for inspection [3&4].

Three examples below show a simple and complex label:

Figure 1 – Simple Label

Figure 2 - Complex label

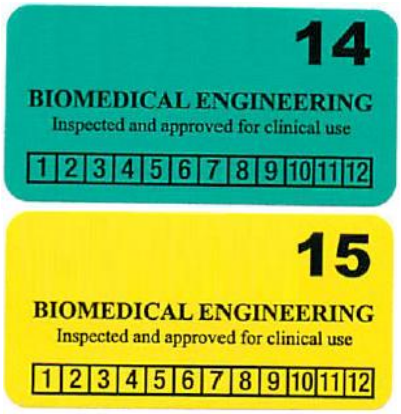

Figure 3 – Exemplary Inspection Due Labels

Inconsistency of Affixing Labels – Medical devices come in different shapes and sizes, there is no standard location on the case to affix the label. BME departments also apply labels inconsistently to medical equipment by affixing to either none, some or all medical equipment. The World Health document on Medical Equipment Maintenance programme overview also suggests affixing a "PM Exempt" sticker on equipment that is not part of the PM program [4].

Social Media – Organizations need to be aware of the presence and potential effects of social media. Consider an injury scenario where an expired label is visible to the patient and others. The situation presents a non-compliant PM that is clearly labelled as such [2]. In a layperson's mind, perception of an overdue PM could be enough to "cause harm to a

patient", leading them to cause unnecessary concerns by exposing the non-compliance on social media.

Privacy – Some inspection due labels record the name or initials of technologist. In a paper based medical device management system this may have been a quick way to assess who last performed the work. However, with a CMMS it is easy to determine who last performed the work by using the equipment control label to look up an asset and the work performed. Recording the name of the individual on the label is no longer relevant.

Infection Control – There is concern that labeling can create an infection control issue. It is possible for biologics to collect around the label, or if the label is removed on the residue when labels are changed.

Accountability – Some departments claim that the inspection due label makes BME more accountable to the public. This is purely anecdotal; there is no metric or data to prove this as a valid assumption.

Risk of Failure – The addition of an inspection due label does not change the risk of the device or the probability of failure of a medical device.

Health Canada – The provinces regulate hospitals, and inspection due labeling is not within Health Canada's jurisdiction.

Accreditation Canada – Section 9.8 of the Required Organizational Practice (ROP) describing a Preventive Maintenance program for medical devices, medical equipment and medical technology does not indicate the requirement to affix inspection due labels [5].

Clinical Engineering Standards of Practice (CESOP) – Section 7.8 Device Maintenance does not indicate the requirement to affix inspection due labels [6].

Diagnostic Accreditation Program (DAP): Services for BME programs often cover Diagnostic Imaging and Laboratory Medicine. Current DAP Accreditation Standards do not indicate the requirement to affix inspection due labels [7&8].

CMBES Position & Recommendation

In-hospital BME departments need to embrace practice change as the healthcare environment and our service evolves. We need to be aware of how our actions (affixing inspection due labels inconsistently) or inactions (not completing PMs on-time) can create misperceptions with uninformed patients and medical staff as to the relative professionalism and efficacy of the BME department. With the explosive growth of social media, we must be in tune with current social media and privacy concerns and make sure we are not exposed to unnecessary concerns by unsubstantiated complaints.

While BME departments may have differing perspectives on the relative usefulness of inspection due labels, it is clear is that current regulatory bodies and professional guidelines do not prescribe the use of inspection due labels.

The CMBES believes that while there are some benefits to affixing inspection due labels, their merit is dwindling. BME departments should begin weaning themselves from affixing inspection due labels, and taking it upon themselves to educate clinical staff and hospital administrators the facts as presented herein.

Recommendation

It is the position of the CMBES not to affix inspection due labels on medical devices.

References:

1) William A. Hyman. The Theory and Practice of Preventive Maintenance, Journal of Clinical Engineering, 2003; Vol 28(1), p31-36.
2) Jerome T. Anderson. The Clinical Engineering as an Investigator and Expert Witness. In: Dyro J, ed. The Clinical Engineering Handbook. Burlington: Academic Press; 2004:44.
3) Russel Furst. PM Stickers Are 'A Waste of Time', Biomedical Instrumentation & Technology; 2012
4) World Health Organization. Medical equipment maintenance programme overview (WHO medical device technical series), 2011. http://apps.who.int/medicinedocs/documents/s21566en/s21566en.pdf. Accessed: August 10, 2015.
5) Accreditation Canada Standard Qmentum Program ver.10. For survey's starting after January 1st, 2016
6) The Canadian Medical and Biological Engineering - Clinical Engineering Standards of Practice 2014 Section 7.8 Device Maintenance
7) Diagnostic Accreditation Program – Diagnostic Imaging http://www.dap.org/CmsFiles/file/2014%20DI%20Standards/DAP%202014%20Diagnostic%20Imaging%20Standards_Complete%20Set_Version%201_2.pdf
8) Diagnostic Accreditation program – Laboratory Medicine http://www.dap.org/CmsFiles/file/2015%20Laboratory%20Medicine%20Accreditation%20Standards/DAP-AS-Laboratory-Medicine-2015-03%20Communications%20Approved%20Version(1).pdf

Caveat: This CMBES Position Statement offers the current stance take by the CMBES on this issue. As new information presents, CMBES reserves the right to change is position.