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DISCUSSION REGARDING C.M.S. REQUIREMENTS FOR LASER SERVICE

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Based on feedback from various hospitals and laser repair engineers it appears that there is some confusion in applying the new CMS rules for maintenance of lasers. It seems to me that the Joint Commission on Accreditation of Hospitals might be misinterpreting the specific documentation requirements of the hospital or third party service providers in maintaining laser equipment. Specifically the presumed requirements that the hospital must have a manufacturer supplied printed PM checklist and specific schedule of service (confused with maintenance) on laser equipment. For the most part these specific lists don't even exist for most medical laser equipment - just the service manuals themselves. Listed below are references to the CMS guidelines and relevant comments concerning applicability.

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From the Dec 2013 CMS memo regarding CFR 482.41(c) stating the requirement for hospitals to provide adequate service .....
From the S&C (Survey & Certification Group): 14-07-Hospital

A. Background: "hospitals comply with this regulation when they perform equipment maintenance in accordance with manufacturer's recommendations. In such cases the hospital is expected to maintain documentation of the manufacturer's recommendations as well as of the hospital's maintenance activities".

COMMENTS: Laser manufacturers do have very thorough laser service manuals. However, many of these (if not most) do not provide any concise PM checklist and many times do not provide a specific schedule of maintenance (service) on their units. A general practice, and recommended verbally by many laser manufacturers' as well, is to provide an annual inspection of the laser equipment.

In addition, separate CFR's (Federal Laser Product Performance Standard) require that service information, including specific calibrations, be made available to the user or others upon request. This is a federal requirement on the manufacturer (not the hospital) and therefore does not directly apply to the

user. In practice most laser manufacturers recommend the calibration check once every year even though it's not usually included in their written information.. This information is useful when interpreting the CMS (Center for Medicaid/Medicare Services) guidelines.

Based on the CMS background statement listed above, a hospital would comply with their regulation (presumably) if they follow guidelines in the manufacturer's laser service manual, whether they had included specific checklists or timelines or not.

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From the Feb 2014 CMS memo (transmittal 103) regarding revisions and clarification of the State Operations Manual (SOM) Hospital Appendix A.....

Interpretive Guidelines CFR 482.41(c)(2)

EQUIPMENT:
" Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified."

COMMENTS:

The only requirement by CMS for personnel to service and maintain the equipment is that the person is "qualified". However, CMS does not specifically say what qualified means, and leaves it at the discretion of the hospital to maintain records of qualifications to demonstrate how it ensures that personnel are qualified to provide such service.

There are several common methods used to document the "qualifications" of individuals performing service work on lasers. The CMS guidelines don't specify what can be used for this but leaves it at the discretion of the hospital. There are two (2) simple requirements in the ANSI (American National Standards Institute) Laser Safety standards (ANSI Z136.3 Safe Use of Lasers in Health Care Facilities) that describes the basic qualifications for individuals to perform service on medical lasers:

1) That an individual has received documented training in laser safety, and;
2) That an individual has received documented technical training commensurate only with the class of laser being serviced and the level of work being performed.

As in other professions, hospitals could presumably utilize the Curricula Vitae's of individuals documenting their experience and training in laser service.

Hospital's could also utilize documentation of training by third party groups of an individual's training in laser service, and these can be provided by the laser manufacturer themselves, or by other educational

groups providing laser service training (i.e. www.LaserTraining.org). Although accreditation is not a requirement, an accredited program would seem to be a stronger indicator or proof of qualifications.

The highest level of documentation for one's "qualification" to perform laser service would be national certification as a laser repair technician. Although not otherwise a legal requirement in any State, it is a professional credential that strongly supports the "qualification" of the individual. These Certifications are available through the National Council on Laser Certification (NCLC - www.LaserCertification.org).

EQUIPMENT (continued):
"Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment."

COMMENTS:
This is the possible point of confusion and contention - following the manufacturer-recommended maintenance activities and schedule. Recently, if Joint Commission inspectors are insisting on seeing a concise PM checklist and schedule that has been provided by the manufacturer, it will not be possible to produce this in most cases. Many of the laser manufacturers do not supply a simple "list" of maintenance activities, nor the schedule of that maintenance. Instead manufacturers' most commonly provide a complete laser service manual, and service personnel can follow these service guidelines for repair, but they probably don't include a specific check list. Common practice in the medical laser industry (by manufacturers and third party service agents) is to provide inspections on equipment once or twice a year (at which time calibration is also checked) and otherwise when a service call is issued due to a malfunction in the equipment. Having the complete service manual available for the lasers being serviced should suffice to comply with this CMS requirement of maintaining documentation of manufacturer recommendations.

A compounding factor in this interpretation of a provided "maintenance schedule" (as listed in the CMS directive), is that the Federal Law requiring manufacturers to provide this information defines "MAINTENANCE" differently than "SERVICE". This is a major point of confusion in the CMS directives. CMS uses the phrase "maintenance" as if it means the technical "service" on the equipment, and this is NOT what the federal law defines. Please see the comments below for further explanation.

EQUIPMENT NOT ELIGIBLE FOR PLACEMENT IN THE AEM (ALTERNATIVE MAINTENANCE) PROGRAM:
"The equipment is a medical laser device". In this section it also incorrectly states that the manufacturer is required by the FDA to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchases and, at cost, to any other parties requesting them."

COMMENTS:
This section in CMS comments regarding FDA requirements for the manufacturer is only partially true. The Federal Laser Product Performance Standard (FLPPS) does require the manufacturer to provide to

the user, and all others upon request, at the "reasonable cost of reproduction" complete information required for servicing the equipment and specifically to include the precise calibration instructions, and other service procedures (implied optical alignment instructions). However, it does NOT require them to provide a "schedule" for service as the CMS memo indicates. The federal law does require that a schedule for "maintenance" be provided by the manufacturer, but even this is frequently omitted in manufacturer service information. Further, the federal law specifically defines "maintenance" as user performed procedures and explicitly differentiates it from the more technical "service" procedures that are performed. Therefore there really is no requirement that the manufacturer supply the actual service schedule, and such a time-line of service is frequently not included in manufacturer supplied service information. This then should be further support for the fact that a hospital or third party provider of service on medical lasers has met the CMS requirements for meeting "manufacturer recommendations" if they have these service manuals available, whether or not they include the specific PM checklists or a suggested schedule of maintenance tasks. Sometimes these manuals will include that information, but most of the time they do not. The federal law does state that the manufacturer should provide this "maintenance schedule" information to users (or others) upon request, so if a hospital wants that information then they should request it from the manufacturer under this law. This however does NOT technically mean an actual technical "service" schedule, according to the law as it is written.

SUMMARY:

The Federal law - the Federal Laser Product Performance Standard - and it's requirements for laser manufacturer's, 21CFR 1040.10 H2II, as alluded to by the CMS memo's can be reviewed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1040.10.

In addition, the second part of that law requiring that specific calibration procedures be provided for that laser device in section 21CFR 1040.11 A2. That can be reviewed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1040.11

There is no requirement that the manufacturers provide a detailed "checklist" for laser preventative maintenance (PM's). There is a requirement that they provide a "schedule of maintenance", but this is rarely provided in manufacturer information, and furthermore "maintenance" in this context (by federal law) does NOT mean a schedule of "service" on the laser.

The industry standard for an average medical laser is for the equipment to be inspected and calibrated at least once per year, sometimes twice per year if suggested. Otherwise the equipment is serviced based upon malfunctions or error codes reported. Some lasers will have suggested maintenance checks performed based on the number of "pulses" emitted by that laser.

There are no standard schedules of maintenance (actually service) which are routinely supplied by the manufacturers. Performing annual checks at a minimum, and following manufacturer recommended practices and procedures in the service manuals would be the industry normative standard in supplying laser service.

About the Author:

Executive Director of the nonprofit Professional Medical Education Association,

Mr. Gregory Absten, has been actively involved in the Medical Laser field for more than 35 years, with an initial background in critical care and surgery in the Allied Heath areas and Critical Care Medicine. He is an internationally recognized lecturer and author on medical lasers, and has taught hundreds of surgical and nursing courses in every specialty over the years. He is founder and Executive Director of the nonprofit Professional Medical Education Association, and chairs the National Council on Laser Certification - a laser credentialing board which provides Laser Certifications to individuals in the areas of medical laser safety officers, laser hair removal specialists, aesthetic laser providers and Laser Repair Technicians. A Scientific Fellow with the American Society for Laser Medicine and Surgery (ASLMS), he served as the Course Director for their "Laser Biophysics and Safety" workshops for more than eight years, and as the Exhibits Chairman at their annual scientific meeting for more than 14 years. He has served on the Board of Directors of the ASLMS in the Laser Safety seat, and has sat on the Education & Training, Safety, and Communications Committees. He is on the Board of Directors for the International Aesthetic & Laser Association (IALA) and the World Association of Laser Applications (WALA), and also sits on the A.N.S.I. Z136.3 Committee for the "Safe use of Lasers in Health Care Facilities".

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