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Diagnostic Equipment in your Practice... What you need to know.

Dear Practice Manager,

My name is Branko Petrovic and I am the Service Manger – Medical & Dental for **IBES Australia** (Industrial, Biomedical, Electronic Services).

It has recently come to our attention that some practices may not be compliant with the requirements of Australian Standards **AS/NZS3551**. As it is important that compliance with **AS/NZS3551** is observed by any Medical practice, we would like to use this opportunity to provide you with some of the main points regarding Service and Service Records.

Outlined below are some of the important points contained within the **AS/NZS3551** standard.

Page 13, AS/NZS3551

“2.3.4.3 Device History

*A history comprising of dates and details of all acceptance procedures, safety and performance tests, modifications and repairs **SHALL BE MAINTAINED.***

NUMERICAL RESULTS OF ESSENTIAL SAFETY AND PERFORMANCE PARAMETER TESTS AND ELECTRICAL SAFETY TESTS SHALL BE RECORDED.

Repair detail shall include description of the problem, details of the work performed (including supplier modifications), labour details including hours worked, details and cost of parts and dates of removal and return to service.”

As you can see from the above extract, documentation that only provides details of manufacturer, model and serial number is not sufficient to satisfy the requirements of AS/NZS3551. Your service provider must provide you with all the numerical values that are obtained and recorded during servicing and testing. Anything less is not considered as compliant.

Page 22, AS/NZS3551

“4.4 Frequency of Testing

An organization shall establish test intervals for the required maintenance and inspection activities so that the risks and hazards are adequately managed. The following factors at least should be considered:

- (a) Manufacturer’s specifications.*
- (b) Knowledge of individual device and usage.*
- (c) Experience with similar equipment, internally and externally.*
- (d) Statutory requirements.*

- (e) An assessment of the impact of failure.*
- (f) An assessment of the location of use.*
- (g) An assessment of the level of use.*
- (h) Service history.*
- (i) The level of pre-use checking by users on regular basis or immediately before use.*

When an organization does not conduct a professional risk management analysis which takes into account the above factors to justify the test intervals, tests SHALL BE PERFORMED AT LEAST ANNUALLY.”

We recommend that all your diagnostic equipment is serviced in 12 monthly intervals rather than 6 monthly (except Sterilizing equipment which we recommend 6 monthly), as this will save you on costs but will still be compliant with **AS/NZS3551**. In the case that some pieces of equipment are used at very high frequency, only these can be serviced at shorter intervals.

For illustration purposes, please find attached an example of an electrical safety test report as outlined by **AS/NZS3551**.

You can use this document to compare against your existing service reports. If the existing service reports do not contain relevant details (similar to attached) as taken from **AS/NZS3551**, then compliance of that service report may be called into question.

If compliance cannot be proven, then safety of user and patient may be compromised.

The second critical report is the performance verification report. To illustrate this, attached is a copy of an example given in **AS/NZS3551**, concerning defibrillator units.

Again, use this to compare against your existing service report.

We believe that it is of paramount importance that safety of user and patient is observed at all times. This is the reason for informing yourself, to the best of our knowledge, the rules and regulation associated with compliance to **AS/NZS3551**.

As a company we strongly believe that only informed customers can make the right decisions. Only decisions made in full knowledge of requirements of relevant standards will be beneficial to your practice and patients.

If we can be of any further assistance please do not hesitate to contact us.

We are happy to discuss your diagnostic servicing needs as well as assisting with designing of tailor made service protocols and comprehensive databases that can be incorporated in your existing practice record keeping systems.

Sincerely,

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