Proposal for periodic verifications of electromedical devices integrated to terrestrial Technical Ambulance Inspection (TAI).

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Summary. In Argentina, electromedical devices may only be commercialized if they meet safety and performance requirements established by current regulations, ensuring their safety and intended performance when leaving the Factory. However, during usage, natural wearing and overloading may change this condition, especially if used in extra hospital services performed by ambulances, which are likely to be subjected to rough handling conditions and hitting. This proposal explains the chosen methodology to address the periodic verification activities of electromedical devices within the process of terrestrial Technical Ambulance Inspection (TAI). Among the results stand out the set of methods for verification and the lists used to record the outcome of this evaluation. Outstanding conclusions include that the operations meet the conditions of an analogous mechanism to that of a Technical Vehicle Inspection (existing for other vehicles), and that the same working structure can be used as a basis for making a manual of procedures for a TAI.

Key words: Inspection, ambulances, electromedical equipment

1. Introduction

In Argentina, the National Administration of Drugs, Food and Medical Technology (ANMAT – Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) is the government entity which regulates the activities related to medical products. The ANMAT, through its disposition 4306/99, approves the MERCOSUR regulation “Essential Requirements of safety and efficacy for medical products”, in order to minimize or reduce failures, the appearance of adverse events and/or malfunction caused by medical devices usage and, at the same time, provide patients, users and other people a high level of protection and provide the functions that the manufacturer has assigned to these devices [1]. It also establishes the enforcement of these regulations for the manufacturers/importers who want to commercialize products of its kind in the country.

In the case of electrical appliances, this means that the equipment must meet safety and performance requirements established by current regulations [2] [3].

The “basic security” and “essential performance” of the electrical appliances are part of the overall security situation, which comprises the safety of: equipment, installation to which it is connected to and the application [4].
The compliance of the regulatory requirements only guarantees that the equipment is safe and performs according to its intended use at the moment it leaves the Factory. However, during usage, natural wear, overloading, misuse or repairs can change its security condition or performance. Thus arises the need for a regular check to ensure that the equipment maintains the security status and initial performance [5].

Ambulances are recognized as a component of pre hospital (or extra hospital) systems and emergency response [6], which is of vital importance for the future of the victim because the probability of death or disability depends on the attention received, at the scene or on route, during the first hour (golden hour) after the event, with special emphasis on the first ten minutes (10 platinum minutes) [7]. Consequently, ambulances are a critical factor in any health system, and the security and proper functioning of the units and equipment must be ensured throughout its lifetime.

Reflecting on the overall security situation of the electromedical devices mentioned above, we see that an ambulance is an environment with singularities which affect the aforementioned condition in areas as diverse as transportation, assembly or positioning, connection, commissioning, operation (often in harsh and adverse circumstances) and position of the operator, his assistants, and the patient, related to electromedical device during use.

Regulations are abundant [8] at both the national [9] and international level [10] which establishes different requirements for both the base vehicle as well as for the elements used in the complex installations of an ambulance. As in the case of medical products, compliance with these standards only assures that the “ambulance” system is safe and works properly prior to its commercialization. Furthermore, the application of these standards is voluntary.

In the regulated field, our country has legislation specifying the minimum conditions to be met by emergency and urgency services but, in practice, there isn’t effective enforcement due to jurisdictional problems [11] and the absence of control mechanisms. Moreover, the scope of these laws is generally limited to listings and input devices to be included within the provided vehicles for the delivery of health care and patient transport.

Taborda and Vanella [12] warn about the need for a TAI, defined as a periodic verification process to confirm the compliance with the safety and performance of these vehicles, considering that it should include the different devices and facilities of an ambulance; based on the general applicable rules to these and other specific regulatory entities when insufficient.

For the effective implementation of TAI, it is necessary to determine which features to test and how to test them, to provide written procedures for each device and installation to evaluate and determine the acceptance criteria for each [13].

In the general context pointed out here, one of the systems to control are the electrical and electronic equipment used for medical practice [12] [14].

The current paper explains the chosen methodology to approach the periodic verification activities of electromedical devices in the process of Technical Ambulance Inspection.

2. Methods

Overall, the verification proposal consists on doing an inspection which involves:

- Visual assessment.
- Functional Operation test.
- Measurements and safety tests.
- Verification of the documentation accompanying the ambulance.
- Systematic recording of previous items’ results.

Even though the activities described are valid to evaluate the electrical appliances of an ambulance, they can also be applied to other subsystems that comprise it.

The operations arising from this study should be conducted under boundary conditions imposed by TAI’s general process [15], such as:

- Being time-efficient (the total duration of ITA does not exceed the seven hours).
• Avoid dismantling equipment and components (except for those essential to test the installation of medical gases).
• Avoid destructive or potentially destructive testing (devices must remain in use after inspection).
• Simplify the tests.

The electromedical devices to check are those established for each ambulance type (A1, A2, B o C) in clause 4.10.4 of the current standard IRAM 16030. For instance, given a type B ambulance:
- Cardioverter Defibrillator.
- Electrocardiograph Monitor.
- Transcutaneous pacemaker.
- Vacuum pump.
- Respirator.
- Pulse Oximeter.

The first task is to verify that each device is registered in ANMAT, in case it fails to comply with this legal requirement, it should not be used.

Then a subset of the total tests defined by the relevant standards must be selected, observing the restrictions imposed by the boundary conditions previously mentioned. The selection criteria contemplate the associated risks due to the use of medical devices and are detailed below:
  a) Recommendations issued by Emergency Care Research Institute (ECRI) [16].
  b) S.O.T. Analysis (Severity, Occurrence, Trends).
  c) Experience of the Multidisciplinary team from the Faculty of Physical and Natural Sciences, National University of Cordoba.

The S.O.T. analysis is a qualitative tool for decision-making, which can be used to prioritize the resolution of problems. The application can be tailored for the task of selecting the set of tests to reflect that the problem in this case, is the risk that affects the patient, operator, other people, other equipment and the ambulance environment; from this perspective we consider that this type of analysis is relevant to achieve our goals because, from its three components, two (Gravity = Severity and Occurrence) are the elements which constitute the risk concept mentioned by the ISO 14971 standard [17].

The S.O.T. consists on describing for each dangerous situation its gravity or severity (severe, serious, not serious), occurrence probability (high, medium, low) and trend or evolution forecast (worsens over time, extinguishes or solves itself, remains stable).

The level for the classification in which each S.O.T. element is divided, is obtained by using a three point Likert Scale [18], modified to express the expert’s opinions about each item. The weight of each point on the scale leads to a representative value of each of the components (S-O-T) of the dangerous situation. The final product of the three values (S x O x T) obtained defines the priorities.

To the selected set of tests, are added those which are established by the IRAM 16030 standard in its clauses 4.10.3.1 to 4.10.3.8 inclusive (except for the “free fall” test and electromagnetic assessment compatibility), which ensure the safety and performance of the devices in mobile situations and field applications. That is, including tests to ensure that, even when the devices withstand rough handling and hitting for being employed on portable and extra hospital conditions, they remain safe and effective.

The resulting tests from the previous selection are classified as: a) common or general (for all devices) and b) particular to each device.

The common set of tests are subdivided into qualitative observations and evaluation of general electrical safety requirements, while the individual tests are done in qualitative observations and safety assessments as well as essential performance for each device.

Finally, verification lists are generated, in which are registered test results.

3. Results
The application of the described methodology results in the following:
**Common qualitative observations**

The items to check are:

1. **Case/Chassis**: examining the outside of the unit in response to the cleanliness and overall physical condition. The case must be intact and the elements between frames (screws, nuts, etc…) must be present and tight. There should be no signs of liquid leakage, or misuse.

2. **Assembly**: if the equipment is fixed to the body of the ambulance or inside a piece of furniture, the supports or fixing elements must be firm and in proper condition to ensure the adequate fastening.

3. **Power connector**: inspect it searching for any type of damage. Exert force on the legs to see if they are firm. Shake the connector in search of noises that may indicate loose screws or broken pieces.

4. **Power Cable**: inspect it for signs of damage. Also check the battery charging cable (if applicable).

5. **Equipment Connectors**: Check its general state; check that it firmly holds the cable connector when connected.

6. **Other device cables**: inspect them searching for possible breaks in the insulation and damage of any kind. Check whether they are mechanically secured on fastening points to the device, so that mechanical requirements during usage are not supported by the conductors within.

7. **Master Switch**: activate it and check that it can be activated freely and that the on/off positions switch forcefully.

8. **Fuses**: check that the fuse in the device is of the type and value indicated on the chassis. Also check for the presence of a spare fuse.

9. **Controls, switches**: check the physical condition of all controls and switches, check if they are securely mounted and that their movement is correct. During the inspection course, check whether each control and switch perform the correct function. If there are any redundant controls, make sure they perform their proper function; then activate them individually and check that the function doesn’t work.

10. **Battery/charger (applies to battery-operated equipment)**: check the physical conditions of all batteries. Verify that the charger is plugged into AC current, and that it’s connected to the device; and also that it has remained like that for long enough. Next, leave the device working using the battery for several minutes to verify it retains the charge. After that check the remaining charge by using the battery status test of the device. An alternative way to evaluate the battery state is by performing the entire inspection with the device disconnected from any other power source.

11. **Indicators/displays**: During the inspection, confirm the correct operation of all leds, indicators, gauges and displays. When appropriate, it should be checked that an adjustment on the display intensity control produces a change on the brightness of the stroke or other information on the screen.

12. **Alarms** [19]: Operate the equipment on a way to provoke the activation of every alarm (both visual and audible alarms. When in doubt, consult the documentation provided by the manufacturer). Check that both visual and audible alarms are produced properly.

13. **Audible Operation warnings** [19]: Operate the device so as to activate all its audible signals. Confirm that the sound level meets regulatory requirements and that the controls work properly.

14. **Labels and markings**: check that all the used units are in SI (International System of Units), with the possible exception of blood pressure. Check that all the labels or control markings are present and legible, as well as operating instructions and conversion tables provided by the manufacturer (in accordance with regulatory requirements).

15. **Accessories**: Check that all required accessories for the device’s normal operation are present and in proper condition.
**Evaluation of general electrical safety requirements**

**Required tools:**
- Automatic electrical safety analyzer in accordance with IEC 60601-1.
- Or else, measuring elements as required by regulations.

The Parameters to be determined during the inspection are:
1. Protective ground resistance.
2. Patient auxiliary current.
3. Patient leakage current.
4. Contact current.
5. Ground leakage current.
6. Power insulation resistance.
7. Applied parts’ insurance resistance.

The correspondent results for the individual tests are presented only for a defibrillator monitor, selected as an example.

**Defibrillator/monitor**

**Qualitative observations**

1. **Pallet/electrodes:** examine the pallets searching for physical damage and observing it’s cleanliness state. Check for dry electrolytic gel remnants, physiological fluids and dirt. Dirty electrodes cause poor electrical contact and can cause burns. Confirm the existence of an adequate number of spare ECG electrodes.

2. **Monitor Performance:**
   I. If the unit can monitor the ECG signal through the paddles, check if the ECG is displayed using as input both the pallets and the hoses.
   II. Inject an ECG simulated signal with known fixed frequency and amplitude, and observe the following:
       a) Baseline: must be horizontal; no significant deviations will be accepted.
       b) The ECG complexes, for a fixed frequency of the simulator, must appear regularly spaced. Check the amplitude and frequency calculated by the monitor.
       c) All portions of the ECG simulated signal must be clearly visible.
       d) Check whether there is interference of 50 Hz or any other significant noise overlapping with the baseline with the ECG simulator connected. Interference in the baseline may appear as a thick line at high gains, but shouldn’t be visible along the lower two thirds of the gain control range.
       e) Control monitor derivation selections, checking it’s possible to obtain all available derivations.
   III. Response to a 1mV step. Press and hold the calibration 1mV button over a period of approximately 3 seconds (or apply externally a 1mV step if the unit does not have this feature available). Notice the following:
       a) The line should show a sharp rising edge, with well-marked and defined vertices not rounded or jagged.
       b) After 3 seconds the level should not drop significantly.

3. **Internal discharge of stored energy:** It must be possible to safely discharge the stored energy in case the medical technician decides not to use the defibrillator after being loaded. With the defibrillator tester’s help, perform a load, activate the discharge button and measure the released energy by activating the discharge from the pallets.

4. **Electrodes:** confirm there is an adequate quantity of good state electrodes at hand (at least 20).
Evaluation of safety and essential performance

Required tools:
- Defibrillator tester in accordance with regulations (e.g.: Fluke 5000).
- Chronometer.

1. Measurement of released energy:
   a) Measure the energy released at 50 Ω load, selecting a max., min. and 2 intermediate energy levels (e.g.: 20, 100, 200 and 360 Joules).
   b) The deviation shall not exceed ±15% or ±4 J, whichever is higher.
   c) The released energy after 30 seconds elapsed since the device is loaded must be >85% from the selected level (check at 360 J).

2. Charging time control:
   I. Charging time at full output power <15 s.
   II. Check that this condition is met even after 5 consecutive discharges (frequency not less than 3 per minute), for E in the last third of the device’s range.

3. Internal Discharge: when disconnecting the device’s power, it should be discharged internally with a <10 seconds time constant.

4. Synchronism:
   I. Connect the patient cable to the ECG tester simulator. Select the synchronism option on defibrillator and perform a discharge.
   II. Check that the time frame from the R wave until the discharge is <80 milliseconds.

5. Defibrillator monitor:
   I. Recovery time after defibrillator discharge <10 s.
   II. Check that the EGC recording is not significantly interfered during charge.

The verification checklists used to register the results presented above are shown in figures 1 to 4 from the following page on.
Figura 1. Example for a checklist of common qualitative observations.

Figure 2. Example for a checklist of general electrical security requirements evaluation.
**Figure 3.** Example for a checklist of qualitative observations for a defibrillator.

**Figure 4.** Example for a checklist of Essential safety and performance evaluation for a defibrillator.
4. Conclusions

- The procedures and the checklists proposed in this work are used to assess the compliance of safety conditions and performance of the electrical devices included in terrestrial ambulances.
- The inspection meets the conditions of a periodic verification mechanism, analogous to a Technical Vehicle Inspection as the one already existing for the rest of the vehicles.
- The Inspection is performed by executing observational assessment tests or measurements and performance verifications, satisfying concepts and security definitions and effectiveness regulations.
- Even though the described activities are valid for assessing electromedical devices in an ambulance, they can also be applied to other subsystems that comprise it.
- The structure of work can be used as a basis for the preparation of a procedures manual for a terrestrial Technical Ambulance Inspection in compliance with the existing boundary conditions.

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