A PREVENTIVE MAINTENANCE AND ELECTRICAL SAFETY INSPECTION SYSTEM FOR A RURAL COMMUNITY SMALL HOSPITAL

by

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I. INTRODUCTION: The Need

In 1975, electronic and electromedical patient care equipment in use in the United States will exceed ten billion dollars in value. The 1975 annual market, alone, for such equipment will be another one billion (1). With X-ray and laboratory generally being the only "money-making" departments of the hospital, spiraling costs pressure the hospital administrator to constantly seek greater economic efficiency. At the same time, competition and community responsibility behoove the hospital to invest in more of the increasingly sophisticated technical marvels as they are added to the medical practitioner's bag of tools. Part of the problem is, then: How to achieve maximum service for the medical equipment dollar.

With the advent of the new consumerism has come the realization that the medical patient is very much in the consumer role. Almost any product or service has the potential to do harm when it is abused. This is especially true of Medicine. Accordingly, the patient's right to accountability in those responsible for medical care delivery has been strongly reaffirmed.

The nature and condition of medical hardware affects the practitioner's ability to meet this responsibility in at least two ways. First, he must be able to rely on a piece of equipment to perform as expected; to cause the desired diagnostic or therapeutic effect. Secondly, medicine, virtually by definition, involves procedures that tread the thin line between benefit and hazard. For faulty equipment to inject hazards of its own making might become construed as negligence, because many of these faults can be prevented or readily corrected.

We are then concerned with the pursuit of three virtues; economy, reliability, and safety. These problems overlap in cause and effect, and

share a common solution; Medical Equipment Control. An equipment control program implies at least three facets: careful selection of new equipment, education of equipment users, and prompt, regular maintenance. The last of these, Preventive Maintenance (PM) may offer the greatest return on the investment of time and money. PM has been standard practice in many sections of profit-oriented industries for several decades. However, because the benefits in the hospital aren't well understood, and because initiating a PM schedule is a lengthy task, it is frequently left undone.

In the following, we propose an approach to preventive maintenance, with special concern for the problems of the small (less than 150 bed) hospital usually associated with a rural community. The system described was designed for Memorial Hospital, a 65 bed facility in Manhattan, Kansas. However, the procedures and philosophies discussed should, in large part, apply to most small and many larger hospitals.

II. PREVENTIVE MAINTENANCE: Philosophy and Practice

2.1 Definition

Preventive maintenance (PM) may be defined as regular, scheduled inspection and care of electrical, electronic, electromechanical and mechanical equipment. The keys to successfully applying this definition are "regular" and "scheduled." The obvious, but often overlooked goal of PM is to correct conditions leading to equipment failure significantly prior to major degradation. The only way this can be met is by ploddingly persistent regularity of attention. Considering the demands of general maintenance a rather rigorous PM schedule is necessary (2,3,4).

There are a number of strong arguments that plant maintenance (primarily mechanical equipment) and medical equipment (mostly electromechanical and electronics) should be separate spheres of responsibility. However, in this discussion, they shall be treated jointly for several reasons. Primarily, few small hospitals can afford to support an engineering-technical staff separate from their plant maintenance department. Even if they can, certain responsibilities will always overlap, e.g., electrical safety with respect to the power distribution grounding system. Also, the concern here is with procedures, records, and scheduling. Comments on work distribution will be made, but local judgement is best applied at this point. In any case, recording and scheduling can just as well be done for both categories simultaneously.

In following the above definition, PM personnel will attend to seven basic considerations for each piece of equipment, where applicable.

1. Is the equipment operating properly? Does it perform its intended functions with satisfactory accuracy and reliability?

2. Is the equipment safe or does it represent an undue hazard to patients or operators?
3. Is the device in good mechanical and electrical condition? Check for loose, damaged, or missing parts, safety shields, mechanical or electrical connections, and strain reliefs.
4. Is there a complete stock of accessories, expendable supplies, and spare parts appropriate to the location?
5. Carry out recommended PM procedures. Special attention should be given to calibrations, adjustments, lubrication, and procedures recommended by the manufacturer as periodic maintenance.
6. Clean the device and accessories. Cleanliness aids in sanitation, improves confidence in the equipment, and makes it easier to observe for proper operation between PM periods. Dirt can also promote degradation of many types of equipment.
7. Record work done for PM records. If corrective maintenance beyond the scope of PM is needed, order it. If the equipment is unsafe, make the appropriate notifications and have it removed from service. For all equipment, but especially critical patient-care devices, make every effort to minimize its time out of service.

2.2 Motivation and Philosophy

One may properly question why such a thorough effort is necessary. The best motivation comes from the hospital's foremost responsibility, the patient's welfare. Toward this, PM will increase equipment reliability on several counts.

First, it is very disconcerting for a nurse to go through an entire stock of a given device, only to find that none of them function properly in a critical situation. Even a device that appears to function well may give

results far from those desired. Surveys have shown many X-ray generators giving excessive doses and many defibrillators delivering energy far below expected levels. Both cases are examples of faulty calibration. The possible severity of such unwitting errors should be obvious.

With preventive maintenance, the frequency and duration of downtime of important equipment should be greatly reduced. Further, with PM scheduling, such downtime can be scheduled to cause minimum disruption, instead of coming at the least opportune moment. Aside from inconvenience and hazard to the patient, every hour that medical personnel spend coaxing balky equipment is expensive maintenance. In addition to the delay and expense of equipment failures, if the device is a charge item, downtime means lost revenue to the hospital.

Proper PM will also reduce the number and severity of accidents and incidents involving equipment failure. When incidents do occur, PM records should prove helpful in investigation of the cause.

Should litigation result from equipment problems, PM will place the hospital on more solid legal ground. The likelihood of equipment failure will have been reduced. PM records can demonstrate that the hospital has made a reasonable effort to that end, and therefore, should not be found at fault. Without regular maintenance, equipment failures and accidents can be construed as negligence. There are many cases of awards and suits against practitioners and hospitals for the use of unsafe equipment, failure to correct defects, and failure to inspect devices prior to use. The National Electrical Code (NEC), Standards of the Joint Commission on Accreditation of Hospitals (JCAH), and the Occupational Safety and Health Act have placed further responsibility on the hospital. PM is a good, commonsense approach

to this problem. The records that document a good PM program are strong evidence with which a hospital can exonerate itself from claims (3,4,5).

PM records can also be designed to gather data on equipment performance, true operating costs, and other points of interest that should be considered in planning future purchases.

In short, the application of PM does not mean equipment will not fail and hazards will not be present. PM does mean that the frequency of such occurences can be significantly reduced and held to a more tolerable level. PM is the "insurance premium" against much more costly problems. The lack of PM is precisely analogous to buying a car with the intent of never checking its oil or lubricating it "until the need is obvious."

Preventive maintenance begins even before a new piece of equipment is put into service, especially when PM is part of a comprehensive equipment control program. Under equipment control, specifications are drawn and made available to prospective vendors, following a set routine. These should clearly spell out minimum performance standards and general conditions that must be met before a piece of equipment will be accepted and paid for. When a device is selected for purchase and arrives for approval, it should be thoroughly examined against the stated criteria as well as normal PM-type inspections. This should be repeated several times throughout the specified trial period and before final acceptance. At this point, the new piece will be in the flow of the PM schedule.

The economic advantage of PM is perhaps most obvious in extending the life of new equipment. Moreover, surveys have shown as much as 40 to 50 percent of new medical equipment bears some defect when delivered (4). A hospital cannot economically or legally afford not to protect itself from this.

There is some argument as to the benefits of PM for older equipment. However, virtually any piece of equipment in service deserves preventive maintenance. PM will retard degradation, extending the life and reliability of a device, regardless of its age when PM is initiated. This should certainly be the rule for patient care equipment. If the device doesn't fit this rule, a patient should not be subjected to it.

A less rigorous attitude may be applied to plant equipment not directly related to patient care. Still, if a device cannot benefit from PM, one must seriously question the economics of keeping it in service at all.

A new factor must be recognized in the judgement to apply PM. It is the finitude of supplies of energy and raw materials, and the limits this places on the national economy. Energy will become increasingly expensive. Materials and manufactured goods may become significantly more expensive. Delivery times may become lengthy and unpredictable. For the hospital, this means energy must be used as efficiently as possible. Also, many equipment replacement decisions have been based on replacement costs versus maintenance costs. This balance may shift significantly, or replacements may simply become unavailable.

In certain instances, PM will cause equipment to use less energy. If equipment availability and replaceability becomes serious, PM will not only be economically sound, it can be a matter of institutional survival.

2.3 Practice

Accepting the benefits of preventive maintenance, a note of restraint must be added. PM can be overused as can any good thing. Careful records can help show when returns don't match the effort, but recordkeeping is not the primary goal. Certain PM checks can, themselves, degrade the equipment. Therefore, PM intervals should be just short enough to reasonably assure

proper performance. At best, 100% reliability and safety can be approached only by expending enough time and money. How much is a hospital (and the patient) willing to pay for a given degree of security? Judgement and experience must point to the optimal amount of PM.

The following criterion is suggested: adjust PM intervals to find defects in about 5% of inspections (1% in critical areas such as ICU/CCU, surgery, and emergency rooms). This level is generally easy to maintain with few personnel. Before a truly life-threatening situation can occur there usually must be a peculiar combination of circumstances. Therefore, this approach tends to provide much better than 95% (or 99%) reliability for a nominal cost. Additional safety and reliability will tend to be very costly and of questionnable value (5,6).

Finally, a program's effectiveness depends on the distinction between what PM is and is not. PM is not repair and overhaul. In a larger hospital, corrective maintenance assignments destroy the effectiveness of a PM employee by disrupting time and scheduling. This person's attention should be on minor adjustments, cleaning, and inspection as outlined above. If a larger problem is found, steps should be taken to protect the device and those exposed to it, and then order the required work.

In labor assignment, judgement again, is a very important tool in PM, especially in the small hospital. With fewer units to maintain and a smaller staff, there must be a balance between corrective and preventive maintenance assignments. An approach is to note that while the total PM staff may be less than one full-time-equivalent, it will probably be several persons, e.g., one for mechanical plant equipment, one for electronics, etc. The same person may do both corrective and preventive work on a given class of devices, but

the two functions should still be separated enough to assure completion of PM schedules. This might mean devoting alternate days to corrective and preventive assignments, or a similar division of time to the same effect.

Whatever approach is taken to PM, the central issue is to give regular attention to each device.

III. ELECTRICAL SAFETY: A Practical Approach

3.1 Hazards

Since the late 1960's, news media have dramatically reported the presence of subtle but significant electrical hazards that are peculiar to the hospital environment. As with most scares, these reports gave rise to considerable panic, and a plethora of solutions. Many of these solutions are highly profitable to the supplier and very costly to the patient. This is not to pass off the problem as minor, nor profitting from it as improper. Patient safety is never a minor concern, and without profits, solutions would be unavailable. Rather, electrical safety is to be approached with knowledgeable moderation and a special eye for the cost to benefit ratio.

This topic has been singled out as a separate topic in this report for several reasons. Primarily, electrical safety has and will continue to foster much controversy and confusion. It is intended here to offer part of an effective, yet economical, response to the problem. Electricity is omnipresent in the modern health care facility. Many equipment malfunctions can cause improper or inadequate results. However, electricity is perhaps the single factor that can, in and of itself, cause death. It can inflict its damage, often without leaving any pathological trace. Despite this, electrical safety is not chasing spooks. Most conditions that might lead to an electrical incident can be readily detected and corrected. Therefore, the regular inspection that is part of effective preventive maintenance can be the first line of defense against electrical hazards.

The hazards due to electricity in the hospital are basically of two types: fire and explosion due to arcing or overcurrent heating in the presence of flammable materials, and physiological damage due to the passage of current through the body.

Fire and explosion prevention are generally a problem of equipment design and selection. From the maintenance standpoint, if one may assume that equipment has been correctly designed and selected, then procedures are essentially those used to verify equipotential grounding integrity to be discussed later. The assumption is, of course, not to be followed without verification, but that is beyond the scope of this paper.

The principle effects of current passage through the body are heating and the stimulation of nerves and muscles. At least one beneficial side effect of the sudden interest in electrical hazards is an increased understanding of these effects. A good overview of the present understanding is found in "Electrical Safety in the Hospital - 1974," by Fred J. Weibell (7).

Briefly, recall that electrical shock is more than one phenomenon. The terms macroshock refers to any shock due to points of contact, none of which are within or near the heart and within the chest wall. A shock received when at least one contact is within or on the heart tissue (myocardium) is called a microshock. A necessary condition for microshock is a conductive path from outside the body to the heart, but elsewhere insulated from the body. A patient in this state is said to be <u>electrically susceptible</u>.

At this time, there are only three procedures in common use that render a patient electrically susceptible:

1. Insertion of a pacemaker catheter electrode from an external pacemaker.
2. Use of a fluid-filled catheter to measure blood pressure in the vicinity of the heart, to take samples from or inject substances into the vicinity of the heart.
3. Insertion of an electrode into a cardiac chamber for intracardiac ECG measurements.

This means only a small percentage of patients confined to specific areas such as ICU/CCU will be involved. However, these also tend to be patients least capable of coping with this added stress. Note that in the small hospital, procedures 1 and possibly 2 will be the only ones commonly encountered (7).

With the exception of microshock, the mechanisms of electric shock are now fairly well understood. The following are accepted as typical minimum stimulus currents for certain reactions (7).

1 milliampere (500 microamperes or greater): Threshold of perception; a slight tingling sensation and startle reactions may result.

10 milliamperes (5 to 15 mA): maximum "Let-Go" current; muscle contractions may be strong enough to prevent release of grasp by the victim. Currents in excess of 18 mA can contract chest muscles, stopping breathing as long as the current is applied. Breathing will ordinarily resume when current is removed.

100 milliamperes (50 to 500 mA): Fibrillation threshold; ventricular fibrillation may occur. The human heart does not normally resume sinus rhythm spontaneously, even after power is removed. Indications are that fibrillation, not suffocation cause most electrically induced deaths.

1 to 5 Amperes: Complete contraction of the myocardium. Normal sinus rhythm will frequently resume upon removal of current. Thus, there is a band of current levels that appear to be more hazardous than higher currents.

These are statistically derived values, subject to individual differences. Since the physiological effects depend on current density, thresholds also

vary with type and area of contact and the skin condition. There are also dependences on contact positions with respect to the heart and with respect to the frequency of the applied current. Unfortunately, the common power line frequencies of 50 and 60 Hertz fall within the range of maximum sensitivity of about 10 to 500 Hz.

The source of greatest controversy is the scarcity of data on microshock in human subjects. Most of the data on which present standards are based is from a relatively small number of experiments on canine subjects. A canine heart has been shown to fibrillate in response to currents as low as 20 microamperes. Mean fibrillation currents are on the order of 100 to 500 microamperes for canine studies (7,8). Human microshock data is limited to perhaps as few as 20 cases. In these, there is no record of fibrillation from currents less than 80 μA, and in some cases, up to 1500 μA was required. Open heart surgery has been the source of almost all human data.

Existing and proposed safety standards (less than 10 μA allowed in susceptible-patient areas) are based on the minimum fibrillation current shown in dogs. This may seem unnecessarily strict in light of the available human data. However, at least one canine study (Graystone and Ledsome, 1973) has shown that a current level well below the fibrillation threshold will block all ventricular contraction as long as the current is applied. In light of this, it is probably too early to relax the microshock safety limit until justified by further evidence (7).

The question then rises, what are the potential sources of these hazardous currents? The Association for the Advancement of Medical Instrumentation (AAMI) has coined the term "risk current" to describe them. Risk currents actually appear by two different mechanisms, not always distinctly separable.

Leakage current, strictly speaking, is that current flowing between conductors that are intended to be insulated from each other. Leakage is due to the imperfect nature of insulating materials and capacitance between conductive surfaces within the device in question.

Fault currents are those due to an unintentional resistive connection to exposed portions of the device. The path may be due to a misplaced wire or component, dirt buildup, spilled fluids, or a variety of other causes.

Common usage tends to lump all nontherapeutic and/or undesirable currents available from a device as "leakage currents." This is generally acceptable, but the distinction should be understood in order to expedite corrective measures.

3.2 Remedies and Standards

Equipment designs that minimize unwanted currents are generally based on chassis layouts that reduce stray capacitance, high impedance isolation in patient circuits, and careful grounding of exposed metal parts that are not intended to be energized. Preventive maintenance for electrical safety consists largely of verifying the integrity of these measures where applicable.

The issue now becomes: With what standards should patient care devices and other electrical equipment used in the vicinity of patients comply and what measurements will adequately verify compliance? The confusion over shock thresholds is clearly reflected in the variety of standards advanced by at least three nationally recognized sources: AAMI, the National Fire Protection Association (NFPA), and the Underwriter's Laboratory (UL). UL's standards are unnecessarily strict and therefore expensive and bothersome. NFPA's research methods and assumptions are under fire from a number of respected ranks. In fact, at this writing,

NFPA's proposing document, 76B-T "Tenative Standard for the Safe Use of Electricity in Patient Care Facilities," has been sent back to committee for revision. This report will follow AAMI's Safety Standard for Electro-Medical Apparatus. This choice follows closely the reasoning of Emergency Care Research Institute (ECRI) in their publication, Health Devices (9).

AAMI establishes two classes of equipment. Type A is that equipment acceptable for use on electrically susceptible patients. Type B equipment is acceptable for patients that are not electrically susceptible. For Type A devices, the maximum allowable leakage from the ungrounded chassis to ground is 100 μA. The maximum allowable leakage from one patient electrode to another or from a patient electrode to ground is 10 μA, whether or not the chassis is grounded. For Type B equipment, the maximum allowable leakage is 500 μA from the chassis and 50 μA from patient leads (9).

All of these limits and precautions are predicated on the intent to maintain safe conditions even in the event of a few typical malfunctions. However, the first line of defense, even if malfunctions remain within reasonable bounds or especially if they don't, is grounding. The tactic here is to maintain all exposed metal, that is not to be intentionally energized, at the same potential.

Assume that all chassis and major metal surfaces have a low resistance connection to ground. Now assume that a ground fault occurs. (A ground fault is an accidental connection between an energized conductor and a grounding conductor, causing abnormally high current in the grounding system.) In this case, excessive current will frequently trip an over-current device, calling attention to and temporarily eliminating the hazard. At any rate, if the ground path is low-resistance, the IR drop will be small,

creating minimal potential difference between the energized surface and surrounding conductors. Similarly, in the case of leakage, almost all of the current will take the ground path as opposed to the higher resistance path through a patient or staff person. A high-resistance ground path will conversely cause significant IR drops, increasing the hazard. Therefore, an inspector should be at least as concerned about the quality of grounding as with the condition in the ungrounded mode.

3.3 Procedure

Electrical safety inspection should include the subset of the following procedures appropriate to the device in question.

1. The line plug should be visually examined to be certain that all prongs, contacts and connections are intact and that the plug is in generally good condition.
2. The line cord and strain reliefs at both ends should be examined while flexed and tugged. Fraying, cracking, excessive abrasion, or other damage calls for a replacement. Tension or mechanical shock on the cord must be relieved so as to place no stress on electrical connections.
3. The grounding resistance between the grounding pin of the plug and exposed metal parts of the device should be measured with a precision ohmmeter. Generally, this should be less than 0.1 ohms. Since it is often difficult to obtain good resolution and accuracy at low resistances, this limit may have to be raised to as high as 0.3 ohms to allow for measurement error.
4. Leakage current should be measured from all exposed metal and patient electrodes to ground and between all patient electrodes. These measurements should be made in all probable modes of operation.

Leakage current can be measured at many points on a device and the device can be connected to power in several ways. Therefore, a complete leakage current inspection involves taking several measurements with the device in different circuit configurations. Some published procedures require as many as 45 leakage current measurements, many of which have been shown to be redundant. Despite this, there is one particular failure mode that can occur in modern isolated ECG amplifiers that commonly goes undetected.

Faulty input isolation amplifiers may inject current from one to another, through the patient. Several published procedures require tests similar to Test 3, following, but make measurements only between lead combinations RA-LA, RA-RL and LA-RL. This is sufficient for older amplifiers in which a differential amplifier is connected directly to LA and RA when Lead I is selected. However, more modern ECG equipment may have isolation amplifiers in each of the patient leads. Failures of the amplifiers in the LL or C leads would not be detected by many presently used procedures.

The following procedure is based on material developed in Departments of Biomedical Engineering within the Veteran's Administration. The procedure is performed in four test configurations and requires only 12 current measurements. Yet, this procedure should detect all probable failure modes of ECG monitors and recorders and is generally applicable to most patient care devices (10).

Selecting a meter with which to measure risk currents requires special attention. The safe current limits quoted previously are actually low frequency values. The body's sensitivity to current varies with frequency. AAMI has adopted the frequency dependence for safe current limits shown in Figure 3.1a. Current limits for Type B devices are 5 times the magnitudes

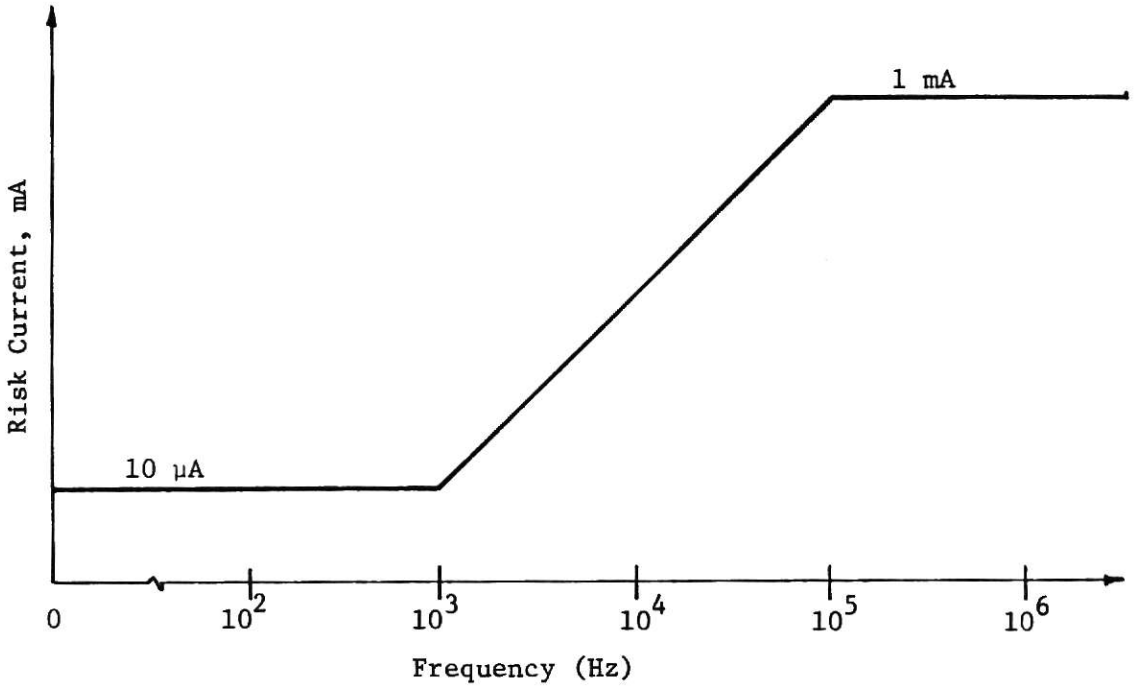

Fig. 3.1a. Maximum Risk Current Limits vs Frequency for Type "A" Equipment.

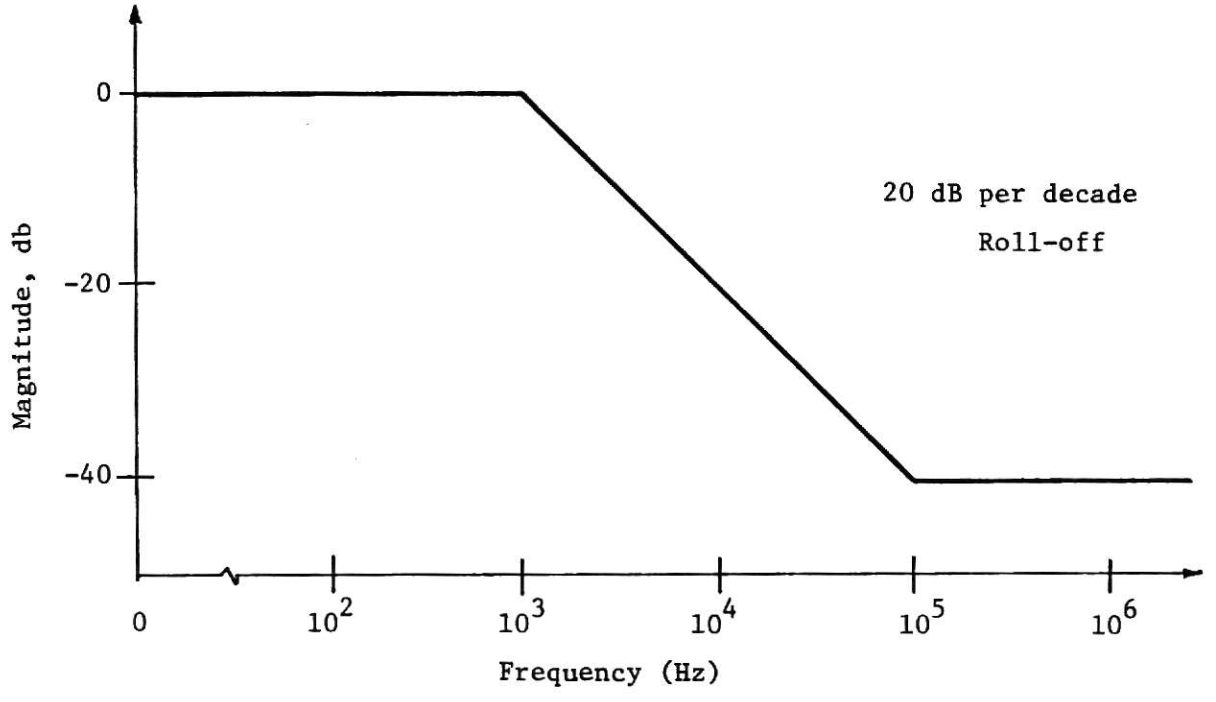

Fig. 3.1b. Magnitude vs Frequency Characteristic of AAMI Test Load.

in Figure 3.1a. It would be bothersome at best to determine the frequency content of risk currents during routine inspections. Instead, a test load can be used for the measurements. Using a load with a transfer characteristic that is reciprocal to Figure 3.1a, the meter may be read as though all leakage is low frequency. The desired characteristic is shown in Figure 3.1b (8).

This characteristic was originally accomplished with networks of the form of Figure 3.2a. At low frequencies, the capacitor appears as an open circuit and the current is imposed on a 1 Kilohm load. By Ohm's Law,

$$V = IR, \quad \text{or} \quad I = V/R, \quad \text{yielding}$$

millivolts/Kilohms = microamperes.

Thus, the millivoltmeter can be interpreted as reading directly in microamperes of risk current.

It has been found that this test load doesn't give accurate results when the source impedance is low and the current contains high frequencies. Assume that the source impedance, Z_s, is large with respect to 1K, and that the millivoltmeter is of high impedance. The risk current, I_r, can then be viewed as a Norton equivalent as in Figure 3.2b, where V_s is the source voltage. Under these conditions, the meter will accurately represent the risk current.

Now, assume the source to be of low impedance. It will then act as a voltage source similar to the Thevenin equivalent in Figure 3.2c. If Z_s is small with respect to 1K ohm, and especially if it is small with respect to 10 ohms, the voltage across the load will not vary significantly with frequency. The desired transfer characteristic is not followed and the meter readings will be erroneously high in the presence of high frequencies (11).

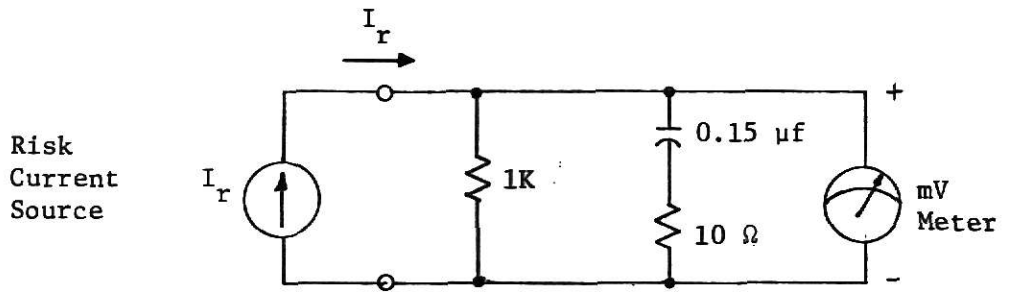

Figure 3.2a. 1974 AAMI Test Load

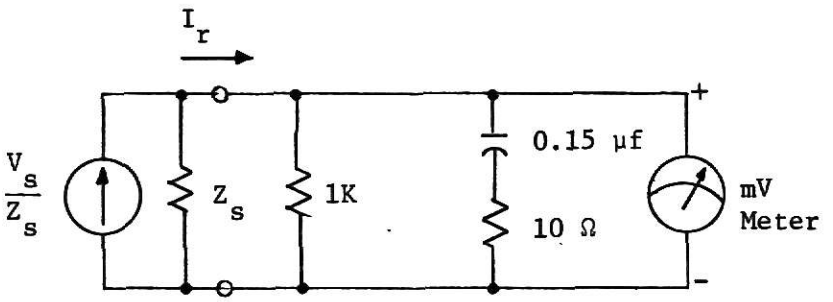

Figure 3.2b. Norton Equivalent Interpretation of Figure 3.2a.

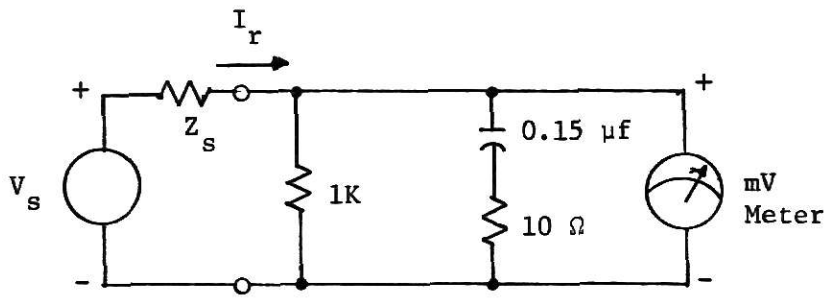

Figure 3.2c. Thevenin Equivalent Interpretation of Figure 3.2a.