The second mode provides the advantage of less signal pollution in the healthcare environment. There is a HAZARD with the second mode, however, if the OPERATOR forgets to enable the generation of ALARM SIGNALS at the appropriate time.

An example of this situation is when an intubated and ventilated PATIENT requires suctioning in a critical care unit. In order to perform the suctioning, the ventilator is disconnected from the PATIENT. This would cause several ALARM SIGNALS to be generated. The time to repeatedly suction the PATIENT can take longer than the maximum AUDIO PAUSE interval and the OPERATOR would instead choose the AUDIO OFF state. After the suctioning is finished, the OPERATOR would have no auditory ALARM SIGNAL. In this situation, it might be preferable to have a REMINDER SIGNAL that the ALARM SYSTEM was put into AUDIO OFF state. After suctioning the PATIENT, the OPERATOR would hear the REMINDER SIGNAL and would be reminded to terminate the AUDIO OFF state.

In other settings, however, the second mode might be appropriate.

Definition 3.37 – ACKNOWLEDGED

The ALARM SIGNAL inactivation state ACKNOWLEDGED differs significantly from the global AUDIO OFF or AUDIO PAUSE. Therefore using the same indication for either AUDIO OFF or AUDIO PAUSE and for this inactivation state would lead to confusion.

When initiating the state ACKNOWLEDGED, the OPERATOR is explicitly acknowledging the presence of the existing ALARM CONDITIONS while at the same time allowing the ALARM SYSTEM to generate ALARM SIGNALS for all other future ALARM CONDITIONS. Furthermore, the ALARM SYSTEM will self-terminate the ACKNOWLEDGED state for a specific ALARM CONDITION when that ALARM CONDITION is no longer true.

This way the OPERATOR acknowledges the fact that certain ALARM CONDITIONS are present, for which the OPERATOR does not want to receive auditory ALARM SIGNALS any more, but that at the same time the OPERATOR wishes to be alerted to any new ALARM CONDITION that might arise to draw attention to a potentially new situation.

EXAMPLE 1 A TECHNICAL ALARM CONDITION that cannot be resolved at the moment or that arises from an intended OPERATOR action, but that can be ACKNOWLEDGED without suppressing PHYSIOLOGICAL ALARM CONDITIONS from other sources not affected by the TECHNICAL ALARM CONDITION.

EXAMPLE 2 Certain PHYSIOLOGICAL ALARM CONDITIONS (e.g. arrhythmia) that are known to be present can be ACKNOWLEDGED without suppressing other ALARM CONDITIONS from the same physiological source.

EXAMPLE 3 A PATIENT on home oxygen is being monitored with a portable monitor. When the PATIENT gets up and moves to a different room, the oxygen saturation falls with exercise. This fall in oxygen saturation is anticipated and it is expected to last only as long as the exercise itself, and then to recover to normal level within a few minutes. This ALARM CONDITION could be an appropriate use of indefinite ACKNOWLEDGED.

In contrast AUDIO OFF or AUDIO PAUSE is frequently associated with disabling the generation of auditory ALARM SIGNALS on a global scale for all ALARM CONDITIONS or a predetermined group of ALARM CONDITIONS.

Subclause 5.2.1 – Instructions for use

[First ~~dash~~ bullet]

OPERATORS have found that in legacy equipment the terminology for the ALARM SIGNAL inactivation states has been ambiguous [18]. This has caused confusion and OPERATOR error when an OPERATOR has accidentally indefinitely inactivated (ALARM OFF, AUDIO OFF) instead of temporarily inactivating the generation of ALARM SIGNALS (ALARM PAUSED, AUDIO PAUSED) due to terminology confusion and inconsistent markings of controls (mode error).

EXAMPLE Some legacy equipment uses the control marking “silence” for ALARM OFF while other equipment uses the control marking “silence” for ALARM PAUSED.

When providing an overview of the ALARM SYSTEM in the instructions for use, it is highly desirable that MANUFACTURERS use the terminology for the ALARM SIGNAL inactivation states that are used in this collateral standard. Writers of particular standards should also use this terminology.

[Fourth ~~dash~~ bullet]

The instructions for use should provide details of any pre-use checks necessary for safe use. [19] These checks could be automatic or be provided by a pre-use checklist. Most equipment will not be fail-safe against a single functional failure such as loudspeaker failure. A faulty loudspeaker can result in an ALARM CONDITION not being recognized due to the absence of an auditory ALARM SIGNAL. To reduce the probability of a FALSE NEGATIVE ALARM CONDITION, the ALARM SYSTEM should be checked at regular intervals.

Long and difficult pre-use checkouts will be resisted by OPERATORS. [20],[22],[24] Ideally, equipment would have an automated or semi-automated checkout to reduce the burden on the OPERATOR. This checkout could include testing of the ALARM SYSTEM, for instance by testing auditory and visual ALARM SIGNALS and asking the OPERATOR to verify their function.

Alternatively, the checkout might include setting the ALARM LIMITS and deliberately introducing a condition that violates those limits, or other means to deliberately generate an ALARM SIGNAL.

Subclause 6.1.1 – General

It can be difficult to classify some ALARM CONDITIONS as to whether they are a PHYSIOLOGICAL ALARM CONDITION (PATIENT-related) or a TECHNICAL ALARM CONDITION (equipment–related).

Subclause 6.1.2 – ~~ALARM CONDITION priority~~ Determination of ALARM CONDITIONS and assignment of priority

ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response or awareness of the situation that triggered the ALARM CONDITION. Priority is assigned through RISK ANALYSIS, either by the writer(s) of a particular standard or by the MANUFACTURER.

NOTE Some ALARM SYSTEMS have OPERATOR-configured or RESPONSIBLE ORGANIZATION-configured priorities.

MANUFACTURERS assign ALARM CONDITION priorities based on RISK ANALYSIS. This RISK ANALYSIS should primarily consider the severity and rapidity of onset of HARM if the ALARM CONDITION is not corrected. It should also consider other factors such as the sensitivity and specificity of the ALARM CONDITION for the actual event in the PATIENT or the equipment. The level of the priority of ALARM SIGNAL only suggests to the OPERATOR the speed at which the OPERATOR should respond to, or be aware of, an ALARM CONDITION. The actual speed of response or awareness required is ultimately based on the assessment by the OPERATOR.

“Immediate” category problems are those that are likely to cause PATIENT injury or death within seconds to several minutes if uncorrected. Few problems fall into the “immediate” category.

EXAMPLE 1 Asystole

EXAMPLE 2 Ventricular fibrillation

EXAMPLE 3 Failure of a cardiac support device (intra-aortic balloon pump, cardiopulmonary bypass machine)

EXAMPLE 4 Sustained high airway pressure

EXAMPLE 5 Extreme hypoxemia

EXAMPLE 6 Sustained high-energy radiation beam

"Prompt" category problems, on the other hand, do not cause PATIENT injury or death until at least several to many minutes have elapsed.

EXAMPLE 7 Many cardiac arrhythmias

NOTE Most cardiac arrhythmias would be prompt or delayed.

EXAMPLE 8 High or low blood pressure

EXAMPLE 9 Apnea (unless prolonged or associated with extreme hypoxia)

EXAMPLE 10 Mild hypoxemia

EXAMPLE 11 High or low pCO_2

"Delayed" category problems cause PATIENT injury only after many minutes to hours have passed.

EXAMPLE 12 Failure of an infusion pump for maintenance of intravenous fluids

EXAMPLE 13 Failure of an enteral feeding pump

EXAMPLE 14 Failure of a PATIENT weighing system

The choice of priority should be based upon RISK ANALYSIS. In general, the lowest priority compatible with the RISK ANALYSIS should be selected. In particular, HIGH PRIORITY ALARM SIGNALS should be reserved for those few ALARM CONDITIONS that truly require immediate response for PATIENT safety—that is, a response within seconds to a couple of minutes. Many types of equipment will not require any HIGH PRIORITY ALARM SIGNALS.

ME EQUIPMENT ALARM SYSTEMS are a protective measure used to minimize risks to PATIENT, personnel, and equipment. In certain therapeutic ME EQUIPMENT, a HAZARDOUS SITUATION could develop so rapidly, and cause injury or damage so rapidly, that OPERATOR response to even a well-designed ALARM SYSTEM would be too slow. In such ME EQUIPMENT, an automatic system of mitigating the HAZARDOUS SITUATION is highly desirable, if not essential. The general standard and many particular standards require such safety mechanisms. It is recognized, however, that no ME EQUIPMENT could have protection against every possible HAZARD, or in the presence of multiple fault conditions.

It should be recognized that, almost without exception, OPERATORS have many additional duties in addition to responding to ALARM SIGNALS. The occurrence of a HIGH PRIORITY ALARM SIGNAL, whether the result of a true positive ALARM CONDITION or a FALSE POSITIVE ALARM CONDITION, generally requires the OPERATOR to immediately stop what he or she is doing and address the cause of the ALARM CONDITION. As an example, the OPERATOR might be in the middle of a sterile procedure on a different PATIENT, and that procedure would be interrupted and delayed by the need to respond to a HIGH PRIORITY ALARM SIGNAL.

A MEDIUM PRIORITY ALARM SIGNAL is also an interruption to the OPERATOR, but it allows a minute or a few minutes for the OPERATOR to finish a brief task before addressing the cause of the ALARM CONDITION, or to find an alternate person who can address the cause.

A LOW PRIORITY ALARM SIGNAL should not interrupt the OPERATOR, but rather the OPERATOR should be able to address the cause of the ALARM CONDITION at a convenient time, for instance, after many minutes, or when he or she next checks the ME EQUIPMENT. Even ME EQUIPMENT that is not continuously attended is checked by the OPERATOR at regular intervals. Events that require interruption of the OPERATOR should not be LOW PRIORITY ALARM CONDITIONS, but rather they should be MEDIUM PRIORITY or even HIGH PRIORITY ALARM CONDITIONS. In addition, if the OPERATOR fails to address a LOW PRIORITY ALARM CONDITION in a timely fashion, the ALARM CONDITION should ESCALATE to a MEDIUM PRIORITY or even a HIGH PRIORITY ALARM CONDITION.

Subclause 6.2 – Disclosures for INTELLIGENT ALARM SYSTEM

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

An INTELLIGENT ALARM SYSTEM need not simultaneously generate ALARM SIGNALS for all active ALARM CONDITIONS. The equivalent safety objective can be achieved by priority ranking and generating ALARM SIGNALS for a subset of the current active ALARM CONDITIONS. When multiple concurrent ALARM CONDITIONS exist, the relative importance of each ALARM CONDITION can be used to internally rank the ALARM CONDITION within a given priority. This internal priority ranking can be used to determine which particular ALARM CONDITION is causing the generation of ALARM SIGNALS or can be used to suppress the generation of ALARM SIGNALS for lower internal priority ALARM CONDITIONS. Multiple ALARM CONDITIONS of the same priority and the same or very similar meaning can also be incorporated into a single message (visual ALARM SIGNAL). These techniques are used to reduce the number of ALARM SIGNALS that an OPERATOR is required to respond to on ALARM SYSTEMS with multiple, related ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS can be an effective way of reducing the number of ALARM SIGNALS that are generated during transient events, thus reducing the number of nuisance or FALSE POSITIVE or FALSE NEGATIVE ALARM CONDITIONS.

To assign an ALARM CONDITION priority, an algorithm of an INTELLIGENT ALARM SYSTEM might consider the magnitude of the deviation of a monitored variable from the ALARM LIMIT, the rate of change of the variable, the duration of the ALARM CONDITION and the presence or absence of any other concurrent ALARM CONDITIONS, redundant sources of information or values of other variables.

After an ALARM CONDITION has generated ALARM SIGNALS, subsequent or persisting ALARM CONDITION(S) can cause the ALARM SYSTEM to change the priority of the ALARM CONDITION or to reassess the initial ALARM CONDITION (and perhaps cancel its ALARM SIGNAL generation) through the use of an INTELLIGENT ALARM SYSTEM algorithm.

INTELLIGENT ALARM SYSTEMS are permitted change characteristics of the ALARM SIGNALS to indicate a change in urgency. These changes can include, but are not limited to, changing the intensity of BURST volume, INTERBURST INTERVAL or PULSE FREQUENCY.

The algorithms of INTELLIGENT ALARM SYSTEMS should be evaluated and validated to ensure that the equipment meets the operational needs of the expected OPERATOR in the expected environment of its INTENDED USE. For methods of evaluation of USABILITY see ~~IEC 60601-1-6~~ IEC 62366.

Subclause 6.3.2 – Visual ALARM SIGNALS

Visual ALARM SIGNALS should indicate to the OPERATOR the presence and level of urgency of any ALARM CONDITION, help the OPERATOR to locate the specific PATIENT or equipment where an OPERATOR response or awareness is required, and identify to the OPERATOR the specific ALARM CONDITION.

There are two requirements for visual ALARM SIGNALS:

– *a "distant" requirement that the presence of an ALARM CONDITION and its priority are correctly perceived from a distance of 4 m (far away); and*

– *an "OPERATOR'S POSITION" requirement that the visual ALARM SIGNAL indicating the specific ALARM CONDITION and its priority are legible from at least 1 m or from the OPERATOR'S POSITION.*

It is possible to comply with the requirements of this collateral standard using either a single visual ALARM SIGNAL or with separate "distant" and "OPERATOR'S POSITION" visual ALARM SIGNALS.

The "distant" requirements are only required when they are necessary to allow the OPERATOR to locate the part of the ALARM SYSTEM that is generating ALARM SIGNALS. The ability to identify the priority of visual ALARM SIGNALS from a distance of 4 m allows the OPERATOR to decide which equipment to respond to first when simultaneous ALARM SIGNALS occur in a multi-equipment environment without having first to go to the OPERATOR'S POSITION.

The ability to discriminate between specific ALARM CONDITIONS and their priorities from a distance of 1 m or the OPERATOR'S POSITION aids the OPERATOR in deciding what actions need to be taken. MANUFACTURERS can choose to also make this "OPERATOR'S POSITION" visual ALARM SIGNAL legible from a distance of 4 m.

The committee considered the use of the standard general alarm symbol and urgent alarm symbol (triangle with 1 or 2 and extended to 3 curved lines) to represent LOW, MEDIUM or HIGH PRIORITY ALARM CONDITIONS. Concern was raised that they are too similar and would be impossible to distinguish on many displays at a viewing distance of 1 m to 4 m.

The committee recognized this limitation, and decided that adding optional elements could be used to indicate the priority.

MANUFACTURERS are free to enhance legibility by any of several means. For instance, the symbols could be colored red or yellow, or placed on a red or yellow background. Additional symbols, letters, or words could be added to these symbols to enhance distinctiveness. One suggestion was to use three identical symbols to indicate HIGH PRIORITY, two identical symbols for MEDIUM PRIORITY and a single symbol for LOW PRIORITY.

Subclause 6.3.2.2.1 – ~~Characteristics~~ 4 m (distant) ~~of~~ Visual ALARM SIGNALS

The committee considered using the triangle symbol (IEC 60417-5307) with 1, 2 (IEC 60417-5308) or 3 curved lines to represent the presence of LOW, MEDIUM OR HIGH PRIORITY ALARM CONDITIONS. Some comments suggested that such symbols were too similar and would be impossible to distinguish on many displays, particularly at a viewing distance of 4 m.

The committee recognized this limitation and decided to allow other methods to indicate priority. For instance, the visual ALARM SIGNAL representing a HIGH PRIORITY ALARM CONDITION could be colored red, or placed on a red background. Additional symbols, letters or words could be added to improve distinctiveness. One suggestion was to use three identical triangles for HIGH PRIORITY ALARM CONDITION, two identical triangles for MEDIUM PRIORITY and a single triangle for LOW PRIORITY.

In Table 2, cyan is added as an option for indicating LOW PRIORITY. Differentiating LOW PRIORITY from MEDIUM PRIORITY by color is an improvement in USABILITY. Historically, only red, yellow and green colored lamps were readily available. A much broader range of colors is readily available today. The committee has chosen one of the complementary colors that is readily available.

Subclause 6.3.3 – Auditory ALARM SIGNALS

The primary purpose of auditory ALARM SIGNALS is to get the OPERATOR'S attention. Additionally, they should help the OPERATOR identify:

– the onset or presence of ALARM CONDITIONS;

– the urgency of the required OPERATOR response; and

– the location of the device generating ALARM SIGNALS.

The requirements of this subclause are intended to ensure that auditory ALARM SIGNALS in equipment are able to fulfill this purpose.

Equipment that is continuously attended by the OPERATOR in NORMAL USE has different auditory ALARM SIGNAL requirements from equipment that is unattended by the OPERATOR in NORMAL USE.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List element ~~a~~ d), first dash)]

Distinctively different auditory ALARM SIGNALS for HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY are specified in Table 3 and Table 4. For any OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, they should be audibly different from other sounds in the PATIENT care area. The HIGH PRIORITY auditory ALARM SIGNAL is designed to be very different from most other sounds (e.g. pagers, telephones, etc.).

The ALARM SIGNALS are priority encoded so that the OPERATOR can readily discern the priority of the associated ALARM CONDITION by auditory means alone.

Mandating the presence of at least one set of auditory ALARM SIGNALS that complies with Table 3 and Table 4 or uses alternative technology (i.e., not based on PULSES and BURSTS) such as voice synthesis ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting one recognizable, standard set of auditory ALARM SIGNALS on all ALARM SYSTEMS. Additional sets that comply with Table 3 and Table 4 and Annex F can be provided without any need for VALIDATION. Additional sets that do not comply with Table 3 and Table 4 can be provided so long as they are priority encoded and are appropriately validated. The RESPONSIBLE ORGANIZATION can configure any one of these as the DEFAULT ALARM PRESET.

Table 3 and Table 4 indicate the difference in priority primarily by the number of PULSES in a BURST and their rhythm. A HIGH PRIORITY BURST comprises 10 PULSES, repeating two identical groups of 5 PULSES with a pause between each group. A MEDIUM PRIORITY BURST comprises 3 PULSES and LOW PRIORITY BURSTS can contain one or two PULSES. Other factors can be used to provide additional priority or relative urgency information. Examples include inter-PULSE interval, inter-BURST interval, PULSE width and other PULSE characteristics. Higher priority auditory ALARM SIGNALS should use faster BURSTS with shorter PULSES that are repeated more frequently than lower priority ALARM SIGNALS.

Auditory ALARM SIGNALS that comply with this standard should sound almost identical to auditory ALARM SIGNALS that comply with ISO 9703-2.

Mandating auditory ALARM SIGNALS in Table 3 and Table 4 ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting recognizable, standard auditory ALARM SIGNALS for an ALARM SYSTEM.

Urgency of the required OPERATOR response is indicated by the different BURST patterns, BURST speeds, PULSE widths, repetition rates and relative volumes that are specified for LOW, MEDIUM and HIGH PRIORITY ALARM SIGNALS in Table 3 and Table 4. Annex D indicates factors that affect the perceived urgency of a BURST. MANUFACTURERS can find this helpful when choosing values that comply with Table 3 and Table 4 and are appropriate for the relative degree of urgency of OPERATOR response to a particular ALARM CONDITION. ESCALATION of ALARM CONDITION urgency within a priority ranking can be indicated to the OPERATOR by similar means.

Auditory ALARM SIGNALS that comply with Table 3 and Table 4 are not required to incorporate melodies. However, if melodies are used, their meanings are required to be as specified in Annex F or be designed so as to preclude the possibility of confusion with Annex F. Annex F therefore attempts to standardize pitch pattern (melody) for the majority of ALARM SIGNALS complying with Table 3 and Table 4.

Often (as has already been stated), many ALARM SYSTEMS generate ALARM SIGNALS in one PATIENT care area. [23] Even if the pitch of all PULSES in a BURST is the same, many OPERATORS can learn to recognize differences in tone, overall pitch, and repetition rate. If the pitch of individual PULSES is varied in such a way as to create simple standard "melodies", the average person can learn to recognize approximately six to eight melodies and to associate them with categories of equipment.

If melodies are restricted in number and are reliably associated with defined equipment categories, OPERATORS are likely to "learn" what a particular melody means and to use this information to help them locate the source of an ALARM CONDITION. If unrestrained proliferation of melodies were to occur, a potentially large number of different melodies would likely be presented to the OPERATOR. This would generate such confusion as to render them useless and potentially hazardous. On the other hand, if all equipment of a given type made exactly the same sound, it might be difficult to identify the source of the ALARM SIGNAL by auditory means in situations where many similar items of equipment are present in one location.

The committee was of the opinion that the RISK ANALYSIS favored some degree of regulation of melodies for ME EQUIPMENT. The challenge was to choose an appropriate degree of regulation without being excessively design restrictive.

The melodies of Annex F were derived by a musically trained subgroup of the experts from the committee. Each melody was chosen to be distinctively different from the others. The assignment of particular melodies to categories was deliberate and based upon a psychoacoustic association between the melody and the category. For more information, see the rationale to Annex F.

MANUFACTURERS intending to use melodies are encouraged to select the most appropriate melody from those in Annex F on the basis of the primary function of their equipment. If they intend to use some other melody, it should not be easily confused with any other melody of Annex F unless the meaning (category) is the same. Note that the defining characteristic of a melody is the relative difference in pitch between successive PULSES in a BURST. Absolute pitch variation is acceptable.

Multi-function equipment can either use one melody that indicates the primary function of the equipment or can apply a different melody to each functional sub-system of the equipment. A specific melody that indicates equipment failure or power down can additionally be used on any equipment in addition to the melody indicating the primary function of the equipment.

[List element ~~b~~ d), second dash)]

A different technology implies something other than electronically generated tones. There are a variety of means for generating auditory ALARM SIGNALS, including buzzers, electronic sound generators and speech synthesizers. At least some of the methods described above can be used to indicate priority regardless of the means of generating the signal.

Table 3 – Characteristics of the BURST of auditory ALARM SIGNALS
Table 4 – Characteristics of the PULSE of auditory ALARM SIGNALS

Table 3 and Table 4 are based on the requirements for auditory ALARM SIGNALS that were found in ISO 9703-2 [26]. These distinctive patterns or rhythms have been used for more than a decade and have been well accepted clinically. Table 3 and Table 4 are slightly different from the equivalent tables in ISO 9703-2. The modifications were intended to simplify interpretation and increase flexibility rather than introduce significant change. Auditory ALARM SIGNALS that complied with ISO 9703-2 should also comply with this collateral standard.

Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the source of the ALARM CONDITION promptly. Ensuring that four or more audible higher-frequency harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. Spatial localization is poor at low frequencies, so the lower acceptable limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz.

Selection of the INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration. Shorter INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for equipment that is intended to be continuously attended by the OPERATOR in NORMAL USE. On the other hand, longer INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to identify, in a timely manner, the source of the ALARM CONDITION. This is particularly true for equipment intended to be unattended by the OPERATOR in NORMAL USE. MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application.

The main differences between ISO 9703-2 and this collateral standard and the reasons for the current requirements, are described below:

a) The new PULSE spacing intervals are defined differently from ISO 9703-2 and provide greater design flexibility. PULSE spacing is now defined as the time from the end of one PULSE to the start of the next. As a result there is no possibility of overlap, which could occur in ISO 9703-2. The actual values permit all auditory ALARM SIGNALS complying with ISO 9703-2, except for HIGH PRIORITY ALARM SIGNALS in which the PULSES almost overlap. For obvious reasons, very few MANUFACTURERS actually did this. The committee considered that PULSES should have reasonable gaps between them, and that near-overlapping of PULSES should not be permitted.

b) In ISO 9703-2, the intended rhythm could not be achieved if each PULSE spacing was the same. The redrafted Table 3 addresses this problem. To ensure that the distinctive pattern is achieved, yet provide some flexibility in overall timing, this standard requires all INTERBURST INTERVALS within a BURST to have the same duration. A tolerance of ±5 % seemed appropriate.

c) The time between the two five-PULSE groups that comprise a HIGH PRIORITY ALARM SIGNAL (time between 5th and 6th PULSES) is now defined as the time from the end of the last PULSE

in the first group to the start of the first PULSE in the next. The equivalent requirement in ISO 9703-2 was defined as the time from the start of the first group to the start of the next. In practice, this time could be unacceptably short. Therefore, few MANUFACTURERS actually complied with this ISO 9703-2 requirement. Instead, they chose the interpretation that is now used in this collateral standard. The intent of the pause was that the first group of PULSES would attract the OPERATOR'S attention, and the second group would emphasize the importance of the ALARM CONDITION and aid in identifying the source of the ALARM CONDITION once the OPERATOR'S attention had been gained.

d) A greater range of INTERBURST INTERVALS is permitted. The existing requirement in ISO 9703-2 is not suitable for ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE. Selection of the most appropriate INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration of the clinical requirement for the ALARM CONDITION in its intended environment of use. Short INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for ALARM SYSTEMS that are always attended by the OPERATOR in NORMAL USE. On the other hand, long INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to promptly identify the source of the ALARM CONDITION. MANUFACTURERS and writers of particular standards are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Factors to consider include:

   – whether the ALARM SYSTEM is intended to be always attended by the OPERATOR in NORMAL USE. In this case a longer INTERBURST INTERVAL is appropriate;

     EXAMPLE Anesthesia machines.

   – the kind of equipment involved;

     EXAMPLE An enteral feeding pump should have a longer INTERBURST INTERVAL than a critical care ventilator.

   – whether the ALARM SYSTEM is connected to a remote DISTRIBUTED ALARM SYSTEM, e.g. a central monitoring system. An ALARM SYSTEM that is not so connected (standalone equipment) should consider a shorter INTERBURST INTERVAL, in order to facilitate identification;

     the presence and effectiveness of additional or alternative notification systems (secondary visual ALARM SIGNALS, vibratory ALARM SIGNALS, ALARM SIGNAL lights in hallways, alarm paging systems, etc). Effective alternative generation of ALARM SIGNALS will permit longer INTERBURST INTERVALS.

e) HIGH PRIORITY auditory ALARM SIGNAL PULSES should be “faster” than MEDIUM PRIORITY auditory ALARM SIGNAL PULSES to ensure that they are perceived as being more urgent. Hence, the requirement that the effective PULSE duration for HIGH PRIORITY ALARM SIGNALS is less than that for MEDIUM PRIORITY.

f) The LOW PRIORITY auditory ALARM SIGNAL is optional, but if present can comprise one or two PULSES. It should be relatively unobtrusive and perceived as less urgent than a MEDIUM PRIORITY ALARM SIGNAL.

g) Pitch is now permitted to rise and fall during a BURST. ISO 9703-2 required that changes in pitch proceed in one direction only. The committee considered this to be without safety advantage and excessively design restrictive.

h) The ISO 9703-2 requirement for the presence of four harmonics has been slightly modified. Reflections and standing waves from pure sine wave auditory signals can make it very difficult to find where they are coming from. Ensuring that four or more audible harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. These harmonics should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of harmonic content can be extremely difficult in simple systems, a value of plus or minus 15 dB (relative sound pressure level) was chosen as a reasonably achievable goal. Decibels were used to express the ratio between the sound pressure level of the fundamental and the sound pressure level of the harmonics because they are commonly used to describe

relative sound pressure levels. The choice of harmonic content is very flexible and permits sounds of very different tonal quality to be created.

i) FALL TIME for PULSES is now less restrictive. It can be any duration that does not overlap the next PULSE. In contrast, ISO 9703-2 sounds were required to have the same FALL TIME as RISE TIME. The committee found this to be excessively design restrictive. MANUFACTURERS are now permitted to create sounds with more distinctive envelopes (e.g. bell-like decays or reverberation effects).

~~– RISE TIME for PULSES is specified as 10 % to 20 % of PULSE duration. There is no significant change from ISO 9703-2. More rapid RISE TIME can be intrusive and startling, but can express greater urgency.~~

– The RISE TIME of a PULSE influences both the perceived urgency and the intrusiveness of the auditory ALARM SIGNAL. More rapid RISE TIMES provide psychoacoustic cues of greater urgency and better reflect the intent of HIGH PRIORITY auditory ALARM SIGNALS, but they can be intrusive and startling. In contrast, slower RISE TIMES are generally perceived as being less urgent, and can be more appropriate for lower priority auditory ALARM SIGNALS or INFORMATION SIGNALS.

With Amendment 1, RISE TIME for PULSES is specified as 10 % to 40 % of PULSE duration with a recommendation that they should not be less than 10 ms. This is a relaxation from ISO 9703-2 and previous versions of this standard. Very short RISE TIMES can cause mechanical distortion arising from the speaker (typically a "thump", "click" or "pop"). Previously the shortest possible RISE TIME was 7.5 ms. This was only possible with a combination of the shortest possible PULSE duration of 75 ms and the shortest possible RISE TIME of 10 %, so this is not a big change. Second, the maximum permitted RISE TIME, which had been 20 % of the PULSE duration, has been doubled to 40 %, permitting even less intrusive or startling auditory ALARM SIGNALS than previously permitted. This can be advantageous for lower priority ALARM SIGNALS or INFORMATION SIGNALS.

– There is no change in the PULSE frequency requirement. Spatial localization is poor at low frequencies, so the lower limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz. MANUFACTURERS can choose any frequency they like from within this range. Higher pitch is associated with greater urgency. [11]

– The difference in amplitude between any two PULSES in a BURST should not exceed 10 dB. Again, this refers to a relative sound pressure level ratio (i.e., not an absolute volume difference in dBA). This requirement is unchanged from ISO 9703-2. It is easier to make all PULSES the same amplitude, but if the amplitude of the early PULSES in a BURST is a little less than subsequent PULSES, it can be less startling.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List elements a) to c) ~~to~~ and f)]

The MANUFACTURER can provide more than one set of auditory ALARM SIGNALS. VALIDATION by USABILITY testing is not required if each set complies with Table 3 and Table 4 (or Annex F). If additional non-standard auditory ALARM SIGNAL sets (i.e., those that do not comply with Table 3 and Table 4 or Annex F) are provided, they require clinical VALIDATION to ensure that they provide at least an equivalent degree of safety as the standard sounds. Permission to provide non-standard sounds is intended to allow a RESPONSIBLE ORGANIZATION to continue to use non-standard but "historically validated" sound sets that have been successfully used for significant periods of time in their PATIENT care areas, and to ensure that this collateral standard is not excessively design restrictive. For example, the RESPONSIBLE ORGANIZATION might prefer some ventilators in their ICU to make one ALARM SIGNAL sound and ventilators of another type to make a different sound. Finally, this flexible approach should ensure that this collateral standard is not

excessively design restrictive and that future development of improved auditory ALARM SIGNALS is not hindered.

When choosing an auditory ALARM SIGNAL set, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the medical auditory ALARM SIGNALS of that set unless their meaning is the same.

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

Sounds from non-medical devices, such as pagers and telephones can resemble medical ALARM SYSTEM auditory ALARM SIGNALS. Care needs to be taken when designing auditory ALARM SIGNALS that the spectral content and amplitude of the ALARM SIGNALS facilitate the localization and identification of the source of the ALARM SIGNAL, taking into account the usual environmental conditions in which the equipment is intended to be used. (See also Annex D.)

NOTE 1 When auditory ALARM SIGNALS are provided, this collateral standard requires that one set of auditory ALARM SIGNALS be encoded to convey the level of urgency of OPERATOR response required. In addition, other sets of auditory ALARM SIGNALS have been devised based on categorization of the nature of the response or awareness and the level of urgency of response required. [18]

A USABILITY test differs significantly from a clinical trial, but is equally important in producing usable, safe equipment. This test spotlights the OPERATOR interface and reactions of the OPERATOR to it. A USABILITY test can take up to a week per use model, depending on the number of OPERATORS involved. Such tests can be conducted in an office-like setting, away from the medical practice environment. This eliminates interference that would occur in the actual-use environment. While USABILITY test formats vary, typically one individual at a time performs self-exploration as well as directed tasks with the equipment. Test administrators can provide special prompts and feedback as required to add realism. As the OPERATOR performs tasks with the equipment, researchers observe and record results. The PROCESS gives the OPERATOR time to concentrate on using the equipment. An OPERATOR can spend weeks learning to use the equipment. Whether they encounter operating difficulties or causes for dissatisfaction over this time depends largely on how much they use the equipment and which tasks they perform. A USABILITY test compresses the initial use experience into a shorter time frame, usually 1 h to 4 h.

In hunting for USABILITY problems, researchers ask OPERATORS to talk their way through each task, describing what they are thinking, decisions they are contemplating, irritants, advantages, and so on. Sometimes USABILITY problems surface immediately, such as when an OPERATOR tries to turn on the equipment and cannot find the power switch. In such a case the OPERATOR can say:

> *Now, I'll turn the power on. I am looking at the front panel but nothing jumps out at me. I see a switch labelled "standby," but I don't think that turns it on. You probably press that button to save power without turning it off. I'm reaching around the back for a switch, but I don't feel anything. I would expect to find a switch right here [OPERATOR points to lower right side of control panel]. This green light probably illuminates when you turn the power on. Oh, I see [OPERATOR presses the light]. This light is the switch. You press it in to turn the power on. That wasn't obvious to me.*

USABILITY test protocols should include frequent USE SCENARIOS and critical USE SCENARIOS. The effect of stress on how an OPERATOR uses the equipment can be studied by introducing time limits, removing equipment labelling, or the OPERATOR'S manual, and introducing equipment failures. Researchers can create a worst-case scenario and see how OPERATORS react. Test