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IEEE Standard C95.1 on Radiofrequency Electromagnetic Field Safety: Considerations of Conservatism

Developed as a discussion paper for IEEE ICES TC95, SC4 & SC3

Prepared by

John Bergeron and Richard Tell
July 16, 2014

Preface

This document is provided by the authors to be used within the IEEE ICES TC95, specifically subcommittees 3 and 4, as a stimulus for discussion of the inherent conservatism in the C95.1 standard for human exposure to radiofrequency electromagnetic fields. As the paper states, we believe that the issue of how the lower tier exposure limits are justified, in the existing standard and its recent predecessors, demands clarification to distinguish their basis from that used to justify the upper tier. Namely, we argue that the language of the standard must recognize the non-scientific basis for the lower tier limits, assuming that a lower tier is maintained as a necessary feature in future standards.

Please note that the format of this paper is intended for ease of committee consideration and discussion; it is NOT in a format suitable for publication in a technical journal. We have sought committee comment on an earlier draft of this document and have attempted to address, where feasible, those comments, for which we are appreciative.

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May 18, 2014

This communication briefly reviews the basis of human exposure limits for radiofrequency (RF) electromagnetic fields developed by the Institute of Electrical and Electronics Engineers (IEEE) International Committee on Electromagnetic Safety (ICES). It explains why some have long maintained that the standard is highly conservative. The arguments expressed here pertain specifically to the underlying whole-body average metric of specific absorption rate (SAR) upon which the IEEE standard was developed based on well-established biological effects. We contend that an additional tier of exposure limits is not justified from any scientific or statistical perspective. Proposed alternative rationales based on localized SAR or non-dosimetrically based exposure limits should be subjected to comparable scientific scrutiny. If validated, a new standard could be formulated.

ANSI Standard C95.1-1982 formed the basis of IEEE Standard C95.1-1991 and its subsequent revisions. The relevant subcommittee at the time (SC4) consisted of 53 members. In the 1982 edition of the standard, SC4 cited 41 references and selected 33 of these for a two-tiered review (first biological, then biological and physical). Under the leadership of A. W. Guy, several fundamental concepts were introduced in the 1982 standard. The first concept was dosimetry with the international standard (SI) unit of specific absorption (SA) of “joule per kilogram” and specific absorption rate (SAR), “the time derivative of the incremental energy (dW) absorbed in an incremental mass (dm) contained in a volume (dV) of given density (ρ)”. The second concept was the identification and selection of the threshold SAR for the change in rate of a learned response in laboratory animals (rats, two species of monkeys) under exposure conditions that maximized SAR (electric field polarized with the body’s long axis). The average value for all species was deemed to be approximately 4.0 W/kg; this SAR value corresponded with an average increase of 0.96°C in the monitored rectal temperature of exposed animals. A tabular summary of these studies was provided in a review of exposure standards by J. M. Osepchuk and R. C. Peterson¹ and is reproduced in Table 1.

The readily reversible behavioral change (change in rate of a learned response) could be regarded as a NOAEL (no observed adverse effect level), although this term was not used at the time. Later it became used as an indicator of LOAEL (lowest observed adverse effect level). A factor of ten reduction of SAR below the behavioral disruption threshold to an SAR of

¹Osepchuk, J.M. and R. C. Petersen (2001). Safety standards for exposure to RF electromagnetic fields. *IEEE Microwave Magazine*, Vol. 2, pp. 57-69, June. and “white papers” in <http://grouper.ieee.org/groups/scc28/sc4/>. Also www.health.mil/dhb/afeb/meeting/041slides/RFR%20STANDARDS.pdf

0.40 W/kg was chosen as the maximum permitted energy absorption rate associated with RF electromagnetic field exposure. The exposure averaging time was set at 0.1 hr, also an approximate ten-fold reduction of the referenced exposure times that were associated with behavioral disruption. The maximum permitted exposure intensity over the frequency range (100 kHz to 300 GHz) was set based on the worst case scenario for energy absorption (E-polarization, whole body) for the range of human body lengths (infant, children, adults). The result was a contour (Figure 2) of incident power density as a function of frequency that would control whole body SAR to no more than 0.40 W/kg, the lowest power density being associated with RF electromagnetic fields in the body resonance range of frequencies (30 MHz to 300 MHz).

Species and Conditions	225 MHz (CW)	1.3 GHz (Pulsed)	2.45 GHz (CW)	5.8 GHz (Pulsed)
<u>Norwegian Rat</u>				
Power Density	—	10 mW/cm ²	28 mW/cm ²	20 mW/cm ²
SAR	—	2.5 W/kg	5.0 W/kg	4.9 W/kg
<u>Squirrel Monkey</u>				
Power Density	—	—	45 mW/cm ²	40 mW/cm ²
SAR	—	—	4.5 W/kg	7.2 W/kg
<u>Rhesus Monkey</u>				
Power Density	8 mW/cm ²	57 mW/cm ²	67 mW/cm ²	140 mW/cm ²
SAR	3.2 W/kg	4.5 W/kg	4.7 W/kg	8.4 W/kg

Figure 1. Comparison of power density and SAR thresholds for behavioral disruption in trained laboratory animals (Table 2 from Osepchuck and Petersen¹)

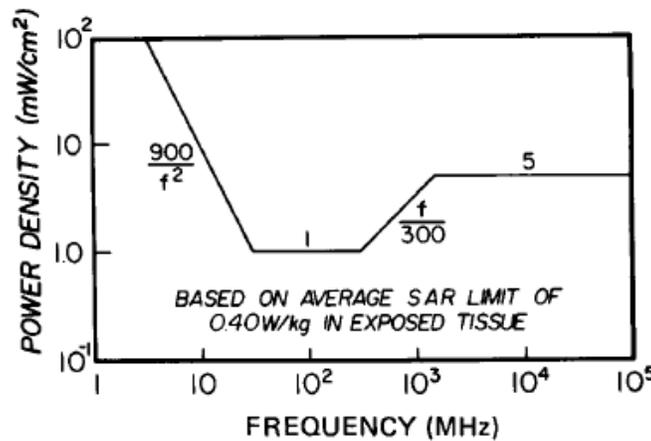


Fig A1
Radio Frequency Protection Guide for
Whole-Body Exposure of Human Beings

Figure 2. Reproduction of Figure A1 from ANSI Std. C95.1-1982.

In subsequent revisions of the standard, an environmental distinction was introduced that led to two levels of maximum permissible exposure (MPE) or whole body SAR. The maximum SAR permitted for the “controlled” environment remained at the original 0.40 W/kg and an additional factor of five reduction (resulting in an SAR of 0.08 W/kg) was applied for the “uncontrolled” environment. This conformed to regulatory agency practice of taking an extra factor for the unknown. It deferred to the concerns of some about chronic exposure (a nominal factor of five ratio of general public to occupational exposure duration) and speculation about “non-thermal” effects. Those concerns are still expressed after 30 years of additional research. Of course, it is never possible to prove the absence of an effect though scientists are receptive to potential new knowledge. The recent 2013 National Academy of Sciences study performed for US regulatory agencies concluded that the former practice of selecting a point and then taking an extra reduction out of concern for the unknown was not “scientifically defensible”. A probabilistic model was recommended as more appropriate². Notably, however, while the report presents in considerable detail appropriate statistical procedures for selecting and testing the appropriate model, it was “purposely refraining” from providing an “acceptable level of risk”. Previously, the EPA had responded to the 1996 pesticide legislation that called for “reasonable certainty of no harm” with a highly detailed and sophisticated interim science policy for probabilistic models and made specific reference to the “threshold of concern at the “99.9th percentile of the distribution of estimated acute...exposure...”³. This position was reiterated by EPA in 2000, in a document “Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern”⁴.

For some members of SC4, the arbitrary factor of ten SAR reduction below the threshold for reversible behavioral change was unsatisfactory because it was not defined by statistical, probabilistic reasons. The public, alternatively, tend to view safety in black and white, not shades of gray. One can find at least 53 dictionary definitions in English for the word “safety”⁵. All are qualitative. Several clarify by reference to being safe in baseball or safety as in football.

In the following presentation, we try to reconcile some of these divergent expectations with respect RF electromagnetic field exposure safety. We will provide reasons to accept the idea that even the basic factor of ten reduction below the average behavioral effect threshold greatly exceeds conventional safety guidelines and even approaches zero. The limit applied to the “uncontrolled” environment (0.08 W/kg) is even more extreme. Our argument might be viewed as the logician’s “*reductio ad absurdum*”.

At the time (1982), it was relatively easy to attain consensus in SC4 for the selection of the SAR threshold for minimal behavioral disruption as the basis for setting human exposure guidelines. The cited (DeLorge et al., several citations in the IEEE review) experimental studies involved several species including two species of primates. The research was state of the art for experimental psychology, as was the physiology and the engineering physics methodology.

² National Academies Press (2013). *Assessing Risks to Endangered and Threatened Species from Pesticides*. ISBN 978-0-309-28583-4. <http://www.nap.edu/download.php?record_id=18344>

³ <http://www.epa.gov/fedrgstr/EPA-PEST/1998/November/Day-05/6023.pdf>

⁴ <http://www.epa.gov/oppfead1/trac/science/trac2b054.pdf>

⁵ See for example: <http://www.onelook.com/>

How to use this threshold (an average of 4.0 W/kg) as the basis for a human exposure guideline was less obvious. Some members wanted a statistics based, probabilistic model while others rejected that model as inappropriate for the phenomena under discussion. It was decided that applying what was thought of as a large margin of safety (factor of ten) to obtain an SAR of 0.40 W/kg was adequate. The philosophical differences, however, remained and the vote to accept the 0.40 W/kg safety level was not unanimous.

In our minds, the best reason for selecting a large arbitrary safety factor was the unsuitability of the reference studies to serve as the basis for a rigorous statistics based safety factor. In fact, the study design known as single subject specifically avoids the necessity of a large number of subjects to infer causality. In behavioral studies, there are two classes of experiments; group studies and single subject studies. Group studies are focused on the population and rely on the statistical procedures familiar to most scientists to validate differences between groups or within a group. Single subject studies, however, are called that because they are focused on the individual. It does not mean only one subject, though commonly the number of subjects is small (N less than 20). Such experiments are a common design in behavioral research of the operant type pioneered by B.F. Skinner. The studies cited as the basis for setting the threshold for reversible alteration of learned behavior are “single subject” designs. Each animal serves as its own control. The single subject design has what is termed “internal validity” and can logically establish causality. The “group study” design is said to exhibit “external validity” but can be confounded when inferring causality from the difference between two groups. There is some controversy about the selection of either study design when the option exists. In the referenced studies with trained primates the option was not available, only single study design was applicable.

Despite the excellence of the referenced research, attested to above, it still suffers from what basic statistics terms insufficient “degrees of freedom”. The very nature of the research using highly trained animals, especially the primates, forced the studies to use few subjects. The number of experiments, however, was large. Establishing and demonstrating a stable reference control behavior is a basic precondition for the single subject design. When the N (the number of subjects) is small (N less than 20), the inference from study statistics (mean, standard deviation, etc.) to the population parameters (μ , σ , etc.) is insufficiently precise to provide a good estimate of the population parameters. It is the quality of inference to the population parameters including valid tests of the “null hypothesis” and appropriate “confidence intervals” that are required for a well-based probabilistic model of safety factors. Clearly, the research selected as the basis for selecting an upper exposure limit for non-aversive behavior change was not designed for and is inappropriate for good inference of the population parameters. However, the replication across species adds substantial qualitative support for the selection of a threshold also relevant to the human. In addition, it is well established (Adair E.R. and D.R. Black white paper⁶) that human thermoregulation is superior to the referenced experimental animals.

It is possible, however, to provide statistical reasoning to support the position that only a very small proportion of a normally distributed human variable is included in the tail bounded by a factor of ten reduction from the mean. The calculation of the “sample” statistics (mean, standard deviation) is independent of the population distribution from which the

⁶ Adair, E.R. and D.R. Black (2003). Thermoregulatory responses to RF energy absorption. *Bioelectromagnetics Supplement 6*:S17-S38.

sample was obtained. The inference of population parameters suitable for prediction of population percentages depends upon the model distribution selected. As noted above, the ability to properly predict depends on the “goodness of fit” between sample data and the selected model. Again, adequate sample size (number of data points) is a consideration in testing whether one of the many potential distribution types is better than another. Procedures such as Kolmogorov-Smirnov, Shapiro-Wilk’s W, Anderson-Darling, etc. are available that test the null hypothesis and can reject a specified model at a given “level of confidence”. In addition, if using probability plots, a linear regression can test agreement with the selected model. In no case do statistical procedures prove the correct model was selected. The best that statistical procedures permit is not rejecting a selected model at a given level of confidence. We never know whether the sample was a deviant as can occur by chance. The conventional 0.05 or 5% confidence level measure assumes that the sample is not as deviant as can occur by chance in one of 20 random samples of identical N obtained under identical circumstances from the same population. Again, the better the data and the larger the N, the better the chance of selecting the correct population distribution and the more precise are the predictions from the model. These considerations are critical to accuracy of predictions in the distribution tails where the available data are thin or nonexistent compared to the central area. Prediction of rare events is a continuing academic and real world concern. The goal of zero defects is the impetus for “six sigma” programs in industry.

Given a set of quality measurements and a good sample size (the better the larger N, (minimum of 20)) a valid inference of population percentages requires the selection and justification of the model distribution that will be used for prediction. A current online statistics program⁷ contains procedures appropriate for considering any of 21 kinds of distributions (Bernoulli to Weibull) and has tests of the null hypothesis capable, at a selected confidence level, to reject an unlikely population distribution as the source of the sample. Statistical software is also available that is devoted to selecting the “best” model and ranking fit among many distributions (50+) of different kinds⁸. Some distributions are identified with specific kinds of measurements like time to failure, or unlikely events. Some distributions have more general utility. One, in particular, the Gaussian, has had such general usefulness that it is called the “normal” distribution. It is the bell shaped curve that is familiar to most people (Figure 3).

Data that originate from complex phenomena and are the result of many interacting, additive factors tend to be normally distributed. If the interacting factors are multiplicative, the result tends to be normal for the log of the observed values. Hence, it is not surprising that measurements in biology tend to exhibit “normality” (mixed factors). Normality can also originate from any distribution if the analysis concerns a sample of repeated measurements. This result is explained by the “central limit” theorem. Note, however, that the theoretical normal is symmetrical (mode=median=mean) and extends from $-\infty$ to $+\infty$, unrealistic real world limits. The theoretical lognormal is asymmetrical (mode<median<mean) with a positive skew and extends from zero to $+\infty$. The upper limit is unrealistic. The restriction to positive values fosters modern use of this distribution, notably in finance and environment.

⁷ <http://statsoft.com/textbook/distribution-fitting>

⁸ Easy Fit, www.mathwave.com

The Anthropomorphic Reference Data for adults and children published by USDHHS compiles data obtained over several years. It covers a wide range of body measurements (35 kinds) for children and adults, by age, gender, race and ethnicity⁹. The results are tabulated

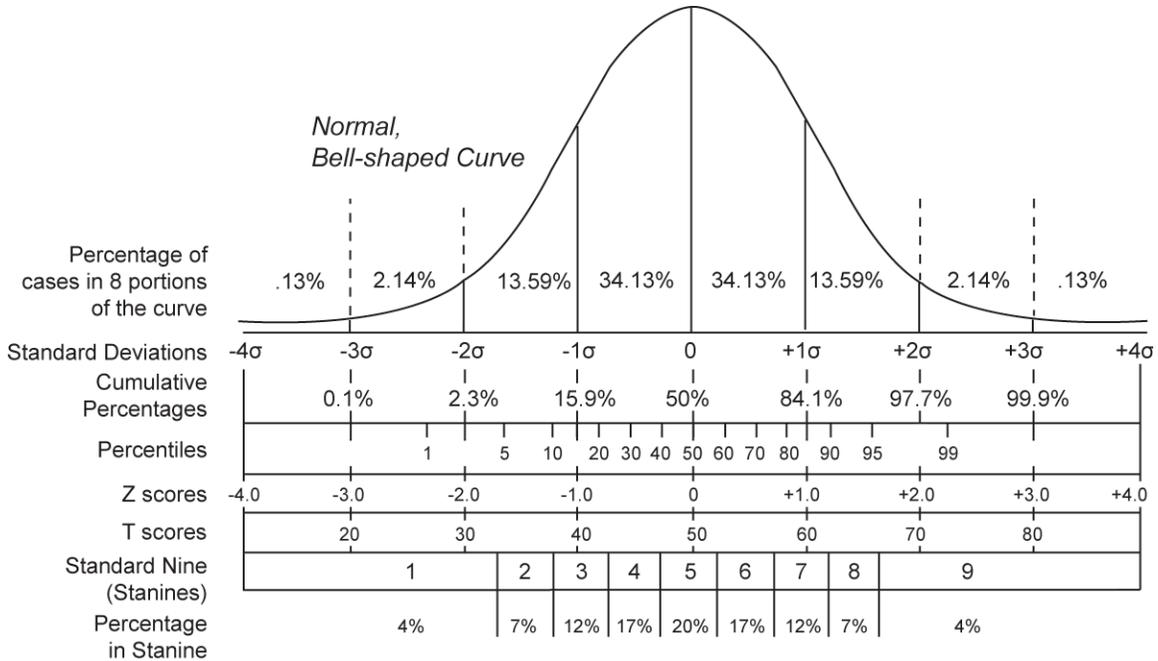


Figure 3. The normal distribution showing percentages of cases in eight portions of the curve, standard deviations, cumulative percentages, percentiles, Z scores, T scores and Stanines.

with N, mean, standard deviation and the number assigned to population percentiles from 5.0 – 95.0 %. If N was inadequate, the row entry noted it. The study used sophisticated statistical design including SUDAAN software that includes distribution tests¹⁰. All the results (1000+) are presented as normally distributed, a testimony to the utility of the normal distribution. Some have argued that the normal model is over used and that often the lognormal is preferable¹¹. It may be more accurate to state that the normal is often applied without adequate justification; namely, adequate tests of the null hypothesis and consideration of other distributions. Note, however, that the shape in arithmetic space¹¹ of the lognormal progressively becomes more normal as the ratio of its mean to its SD increases though positive skew and the lower bound of zero remain. This progression is well illustrated in Figure 4 of the cited Limpert et al.

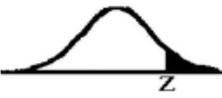
One long studied human variable is intelligence; commonly expressed as the IQ (intelligence quotient) with a μ (population mean) of 100 and σ (standard deviation) of 15. One may pose the question: What percentage of the population would have an IQ of 10 or less? How many sigma units (Z score) below the population mean is an IQ of 10? The answer is -6 (Z score = $[(10 - 100) / 15]$). This is well beyond the 3-sigma limits commonly

⁹ www.cdc.gov/nchs/data/series/sr_11/sr11_252.pdf

¹⁰ SUDAAN@rti.org

¹¹ E Limpert, et al., *Bioscience*, May 2001, V. 51, No. 5, 341-352.

used to include 99.7% of a normally distributed population with 0.15 % in each tail. Readily available Z reference tables rarely extend beyond 3.0 – 3.5 sigma. A direct calculation from the integral for the normal distribution requires more than seven-digit ability to go beyond 5 sigma. The proportion in the extreme tail with an upper bound of -6 sigma is given as 9.866 E-10 (see Figure 4). This estimate can be expressed as 1 chance in 1,014,713,328¹². For most purposes, this can be regarded as zero chance; thus, essentially, 100% of the population is included above -6 sigma. Even if, in fact, the normal were not the best fit in the extreme tail, the factor of ten still would include extremely few or no people. This probably satisfies the general public expectation of what it means to be safe if it were applied to an exposure standard. In particle physics, as in the recent claim of the discovery of the Higgs Boson, the claim was justified by rejecting the null hypothesis at 5-sigma. More recently the rejection reached 5.9-sigma, or "...surer than sure"¹³.



**Far Right
Tail Probabilities**

Z	P{Z to ∞}	Z	P{Z to ∞}	Z	P{Z to ∞}	Z	P{Z to ∞}
2.0	0.02275	3.0	0.001350	4.0	0.00003167	5.0	2.867 E-7
2.1	0.01786	3.1	0.0009676	4.1	0.00002066	5.5	1.899 E-8
2.2	0.01390	3.2	0.0006871	4.2	0.00001335	6.0	9.866 E-10
2.3	0.01072	3.3	0.0004834	4.3	0.00000854	6.5	4.016 E-11
2.4	0.00820	3.4	0.0003369	4.4	0.000005413	7.0	1.280 E-12
2.5	0.00621	3.5	0.0002326	4.5	0.000003398	7.5	3.191 E-14
2.6	0.004661	3.6	0.0001591	4.6	0.000002112	8.0	6.221 E-16
2.7	0.003467	3.7	0.0001078	4.7	0.000001300	8.5	9.480 E-18
2.8	0.002555	3.8	0.00007235	4.8	7.933 E-7	9.0	1.129 E-19
2.9	0.001866	3.9	0.00004810	4.9	4.792 E-7	9.5	1.049 E-21

Figure 4. A public domain table of the normal distribution listing the far right (Z) or far left (-Z) tail probabilities. Table found at <http://www.math.unb.ca/~knight/utility/NormTble.htm>.

The distribution of a human variable central to the physiological response to radiofrequency electromagnetic field exposure and energy absorption is body temperature. In the referenced squirrel monkey experiments, the rectal temperature elevation that correlated with behavioral disruption was 0.96°C. In a study of 148 subjects (aged 18 through 40 years), Mackowiak, et.al. (1992)¹⁴ measured oral temperatures resulting in some 700 measured values representing temperatures at 2-4 different times of day on 2-3 successive days. The temperatures were measured with a digital probe (Datatek, Inc.) on 2-3 consecutive days in preparation for entry into vaccine trials. The authors' assumed normality "Because initial descriptive analyses suggested neither strong kurtosis nor skewness." The analyses were

¹² <http://fourmilab.ch/rpkp/experiments/analysis/zCalc.html>

¹³ <http://www.popsci.com/science/article/2012-08/new-lhc-results-we-were-sure-we-fond-higgs-boson-and-now-were-even-surer>

¹⁴ Mackowiak, P.A., Wasserman, S.S., and Levine, M.M. (1992), "A Critical Appraisal of 98.6 Degrees F, the Upper Limit of the Normal Body Temperature, and Other Legacies of Carl Reinhold August Wunderlich." *Journal of the American Medical Association*, 268, 1578-1580.

performed on an IBM PS/2 with SAS-PC software. The overall mean was given as 98.2 ± 0.7 °F. Whisker plots of the data grouped by time of day (6 AM, 8 AM, 12 PM, 4 PM, 6 PM, 12 AM) provided 5, 50, 95 and 99 percentiles. A histogram of all 700 data points with male and female identified was provided. The histogram was used by Shoemaker¹⁵ to generate a data set of 130 oral temperature values with equal numbers from both males and females (data available at link below)¹⁶. These data have the same mean, standard deviation and range as the original 700 values. These data have been used widely in various university courses to illustrate statistics procedures^{17,18} and as an example by organizations providing statistical support¹⁹. A mean oral temperature of 98.25 °F, standard deviation (SD) of 0.733 °F and standard error of the mean (SEM) of 0.064 °F were obtained.

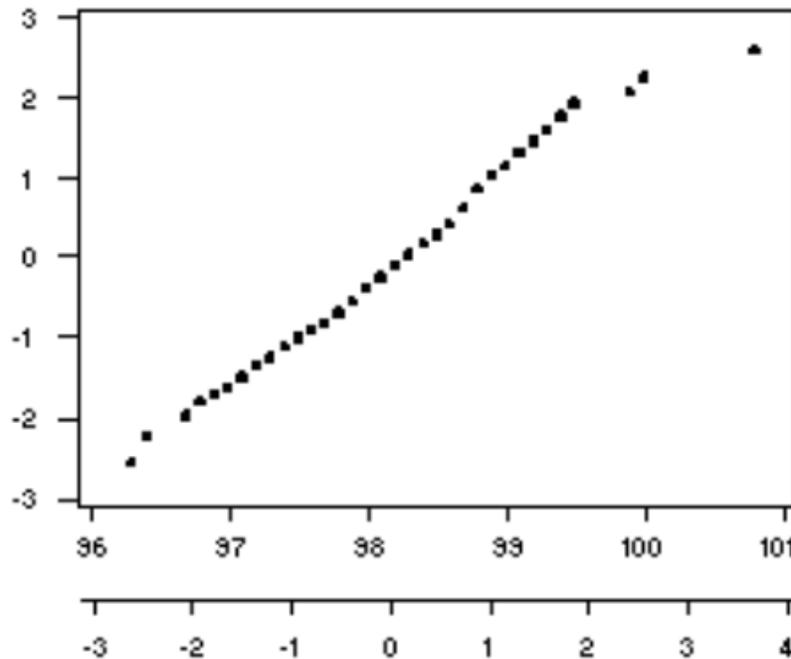


Figure 5. Yale q-q probability plot of data on oral temperatures¹⁸. The vertical axis corresponds to the normal quantile values vs. the observed temperatures and standardized values on the horizontal axis. The close correspondence between the normal and standardized quantile values (slope ≈ 1) indicates that the data appear to be from a normal distribution.

The q-q probability plot, from the Yale course¹⁶ in Figure 5, is satisfactorily linear.

¹⁵ Shoemaker, Allen L. (1996). What's normal? – temperature, gender and heart rate. *Journal of Statistics Education*, Vol. 4, No. 2.

<http://www.amstat.org/publications/jse/v4n2/datasets.shoemaker.html>

¹⁶ Data set at <http://www.amstat.org/publications/jse/datasets/normtemp.dat.txt>

¹⁷ <http://www.stat.ucla.edu/~rgould/m12s01/ttest.pdf>

¹⁸ <http://www.stat.yale.edu/Courses/1997-98/101/normal.htm>

¹⁹ StatPoint Technologies, Inc., Warrenton, VA; http://www.statgraphics.com/basic_statistics.htm#outlier
 Contained in Statgraphics User Manual for StatgraphicsCenturionverion XVI available online also in outlier identification FEM.pdf (from Rev.1/11/2005).

The more detailed analysis from StatPoint determined that only a single point (the highest) would be rejected by Grubb's test for outliers. In addition, several tests of the null hypothesis including the rigorous Shapiro-Wilk ($p = 0.821$, a version with N extended to 2000 by Royston²⁰) supported the acceptance of normality. The linearity of the probability plot was supported by linear regression. Separately, we performed the Anderson-Darling test ($p = 0.1537$ ²¹ to 0.1746 ²²) which also supports the selection of the normal distribution. These two tests, of different types, are the most powerful for rejecting the null hypothesis for the normal distribution when tested by Monte Carlo simulation with many samples of increasing N from several other hypothesized population distributions²³. Calculation with the EasyFit⁸ software indicates that the null hypothesis is not rejected at the 0.01 level for either the normal or the lognormal, but ranks the normal the better of the two. This software ranks the 3 parameter Burr test even higher but that may be over-fit. The probability density plots of the two fits in the observed units superimpose as shown in Figure 6. The actual differences are very small over the range of the sample values. Even if the lognormal or the 3 parameter Burr actually were the source of the sample data, it can be argued (*vide infra*) that the lower tail predicted by the normal provides the more conservative estimate for a safety factor.

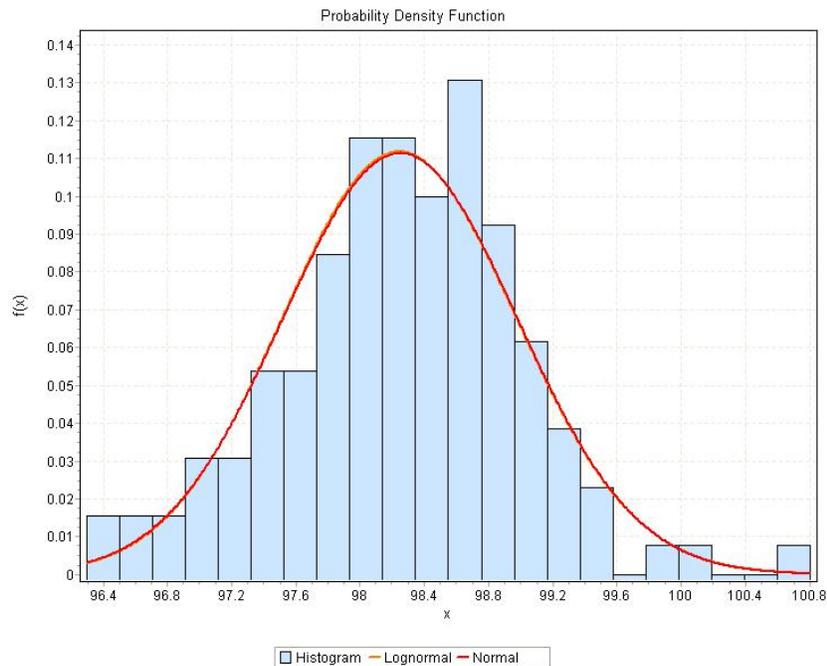


Figure 6 . EasyFit Plot of the Normal and Lognormal fits over a 22-bin histogram of the 130 person human oral temperature data. There is no perceptible difference over the observed range of data, the two appear superimposed.

²⁰ Royston J.P. An extension of Shapiro and Wilk's W test for normality to large samples. *Applied Statistics* 31: 115-124, 1982.

²¹ <http://xuru.org/st/DS.asp>

²² <http://www.spcforexcel.com/anderson-darling-test-for-normality>

²³ N.M. Razali and Y.B. Wak, J, *Statistical Modeling and Analytics*; Vol.2, No.1, 21-31, 2011.

Remembering that the lognormal has an inherent positive skew and that transformation from observed to normal shape and back requires shifts from arithmetic space to log space and back, the calculation of population % in tails is not intuitive. For our purposes here, it suffices to show that the normal offers the more conservative estimate.

A comparison from Peter J. Ponzio's tutorial comparing normal and lognormal distributions²⁴ (Figure 7) shows how the lognormal is skewed and places more than 50% above the mean whereas the normal is symmetrical and has the "fatter" lower tail. For lognormal distributions as the ratio of its mean to the standard deviation increases the shape approaches the normal but is still skewed to the right. As a result, the population percentile in the left tail of the normal is larger.

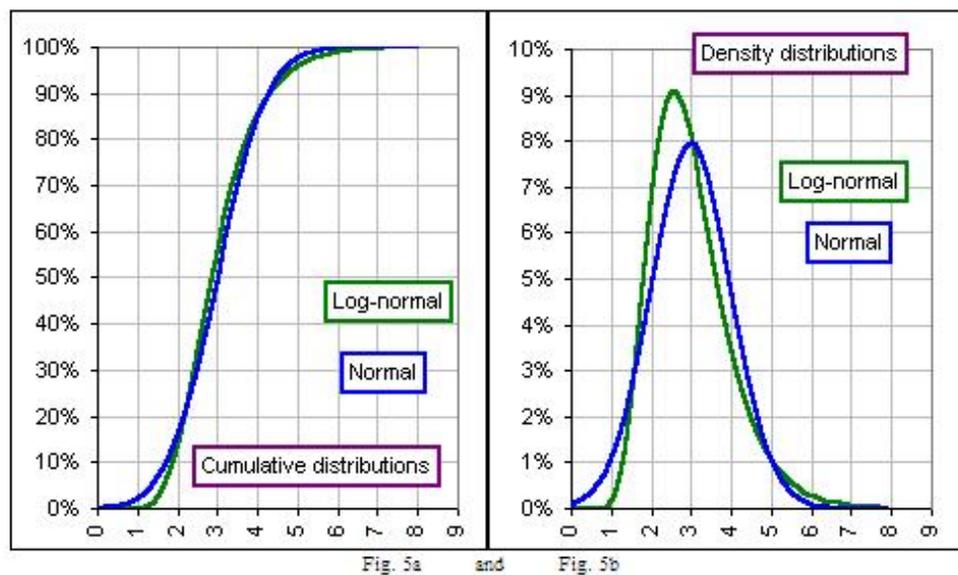


Figure 7. Comparison of normal (blue) and lognormal (green) cumulative and density distributions for observed values when the shape of the lognormal approaches "normal".

Accepting the normal distribution model, we can ask about the likelihood of observing an oral temperature of 9.825 °F (one-tenth of the mean value) or less in the population. In this instance the Z score ($z = [9.825 - 98.25] / 0.7333$) = -120.6. Again, the model places 100% of the population above a value equal to 10% of the mean. In this instance the absurdly low probability (even a 15 decimal calculator returns zero) reflects the small standard deviation used to estimate sigma. The small standard deviation, in turn, reflects the excellent autonomic control of human body temperature. Since control of core body temperature is the basic physiological response to energy absorption, regardless of source, this distribution probably best defines the thermal response to whole-body radiofrequency electromagnetic field exposure. It is specifically relevant to consideration of safe exposure.

²⁴ P. J. Ponzio. http://www.financialwebring.org/gummy-stuff/normal_log-normal.htm

One well-defined human distribution that is directly relevant to exposure to RF electromagnetic fields at lower frequencies has been considered by the IEEE ICES SC3; namely, contact with a source of alternating current (60 Hz). Electric shock from 60-Hz current was studied extensively many years ago by C.F. Dalziel²⁵. An equivalent to the NOAEL was the perception threshold for electrical current flow in the hand. Data were presented for 167 male subjects. The normal probability plot was very linear with a mean of nominally 1.1 mA. The SD was not given but the supplied plot with percentiles from 0.2 to 99.8 (see Figure 8) includes 99.6% of the sample population, which approximates the classical ± 3 sigma (6-sigma range) of 99.7%.

The limits of the range of the plot between 0.2 and 99.8% were deliberate. Dalziel objected to the mathematical concept of a distribution that extrapolated the threshold to extreme low values²⁶. He contended, "This is obviously untenable". It is possible, however, to extract from the graph an SD of 0.24 mA. A calculation of the Z score for the value of one tenth of the mean $[(0.101 - 1.01)/0.24]$ is -3.77 . The probability is 0.00007235 or 1 in 13,831. The greater probability compared to the prior two examples reflects the greater variability in the subjective sensation reported by individuals. The selection of a further reduction would provide a greater margin if desired.

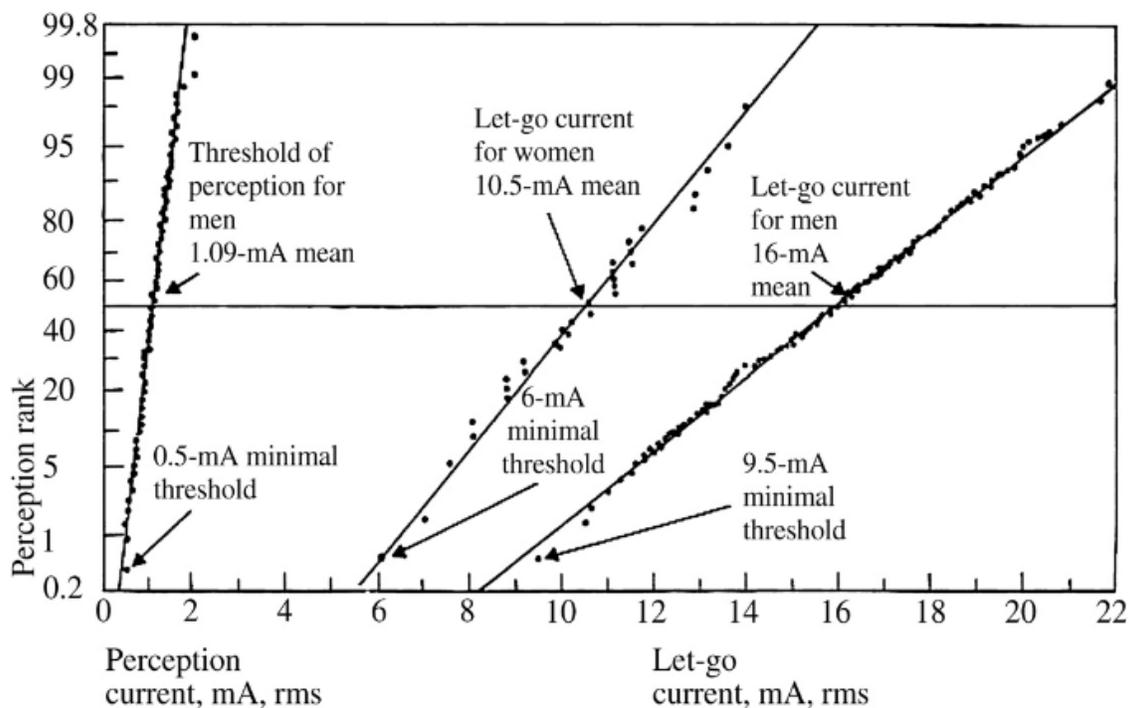


Figure 8. Replotted from C. F. Dalziel, "Electric Shock," *Advances in Biomedical Engineering*, edited by J.H.U. Brown and J.F. Dickson III, 1973, 3, 223-248.

²⁵Dalziel, C. F. (1972). Electric shock hazard. *IEEE Spectrum*; Vol. 9, No. 2, Feb. p. 41-50.

²⁶ Meeting of experts on electrical accidents and related matters, Geneva 23-31 October 1961 International Labour Office, Geneva.

The three examples provided here should suffice to show that a factor of ten reduction on the mean of a human variable falls in the lower tail of the normal distribution and can reasonably be considered *ipso facto* safe. Another way of saying this is that a whole body average SAR of 0.40 W/kg cannot be expected to result in any behavioral disruption. An additional factor of five to achieve one fiftieth of the mean SAR for behavioral disruption as used for “uncontrolled” environments is obviously *reductio ad absurdum*. We believe that the basis for the IEEE standard, whole body SAR that results in behavioral disruption, is consistent with the conclusion that a safety factor of ten is entirely sufficient for protection against adverse health effects and, further, a value this large is likely not necessary. Certainly, the application of a safety factor of 50 is not justified by any reasonable judging of the data and unnecessarily complicates the matter of explaining the highly conservative nature of the standard to workers and the public. We argue that future standards for human exposure to RF electromagnetic fields should be based solely on scientific knowledge and completely abjure speculative, socio-political criteria. If, however, political considerations of the need to “harmonize” with Europe dictate the second tier, then the standard should explicitly acknowledge that fact rather than implicitly validate anti-science concepts^{27 28 29 30} such as “Prudent Avoidance” (PA) or the “Precautionary Principle” (PP) or “Post-Normal Science” (PNS). Even the European Commission, in advocating proportionality of PP, explicitly acknowledged the political basis, as have, even, some scientific supporters^{31 32}. At the extreme position, some, such as the United Nations’ UNESCO COMEST judge it unethical not to apply PP³³. The need for an environmental lower tier to consider phenomena such as RF interference has been advocated³⁴.

An attempt to reconcile science and politics in C95.1-2005 is clear on page 2 of the standard in section 1.3 INTRODUCTION that reads as follows:

²⁷ Prudent Avoidance: The Abandonment of Science. (Official Position of EEPa, 1991). Health Physics Society Newsletter, October, pp. 21-24.

²⁸ Communication from the Commission on the Precautionary Principle; <http://eur-lex.europa>. Eu/Com 2000 0001 en 01.

²⁹ A. Stirling “Science and Precaution in the Management of Technological Risk” (1999) ESTO project ISpra, <http://ftp.jrc.es/EURdoc/eur19056en.pdf>

³⁰ Ravetz, J. R., NUSAP – The Management of Uncertainty and Quality in Quantitative Information. <http://www.nusap.net/sections.php?op=viewarticle&artid=14>

³¹ Foster, K., et al. Science and the precautionary principle, *Science*, New Series; 28(4). pp 970-980 (2000).

³² Keifets, L., et al; The precautionary principle and EMF, implementation and evaluation. *Journal of Risk Research*, 4(2) pp113-125. (2000).

³³ UNESCO COMEST. The Precautionary Principle, March 20 (2005)

³⁴ Osepchuk, J. M. Environmental Standards: the new concept and key to international harmonization of safety standards for the safe use of electromagnetic energy. IEEE Intl. Symposium on Technology and Society, ISTAS '04, pp. 165-173, 2004.

Two tiers of exposure limits have been established. The upper tier, which is protective for all with an acceptable margin of safety, applies to exposure of persons in controlled environments. While the weight of scientific evidence supports the conclusion that there is no measurable risk associated with RF exposures below the upper tier of this standard, it is scientifically impossible to prove absolute safety (the null hypothesis) of any physical agent. Thus the lower tier, with an additional safety factor, recognizes public concerns and also supports the process of harmonization with other standards, e.g., the NCRP recommendations [B95] and the ICNIRP guidelines [B62]. The lower tier also defines the action level above which implementation of an RF safety program is recommended. The BRs and MPEs of the lower tier may also be used for the general public to address concerns of continuous, long-term exposure of all individuals.

We propose that a substantial improvement in language supporting the scientific concept of safety might be accomplished by a few simple changes in the C95.1-2005 paragraph quoted above, as follows:

“The upper tier is protective for all with a large measure of safety. While the scientific evidence supports the conclusion that there is no risk associated with RF electromagnetic field exposures at or below the upper tier, it is not scientifically possible to prove the absence of risk. The lower tier’s additional reduction addresses public concerns and harmonizes with other recommendations and guidelines such as NCRP and ICNIRP”.

This revised narrative is consistent with the substance of our discussion of the very high margin of safety (even ‘safer than safe’) from whole-body thermal effects of energy absorption from exposure over the relevant frequency range provided by the upper tier exposure limit (0.40 W/kg whole-body average). Further, the inherently anti-science, political origin of the lower tier limit of 0.08 W/kg whole body average is recognized.