

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of)	
)	
Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies)	ET Docket No. 13-84
)	
Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields)	ET Docket No. 03-137
)	
)	

To: Office of the Secretary
Federal Communications Commission (FCC), Washington, DC 20554

As officially presented in the Federal Register/ Vol. 78, No. 107 / Tuesday, June 4, 2013 / Proposed Rules. Federal Communications Commission, 47 CFR Parts 1, 2, 15, 24, 25, 27, 73, 90, 95, 97, and 101 [ET Docket Nos. 03-137 and 13-84; FCC 13-39], Reassessment of Exposure to Radiofrequency Electromagnetic Fields Limits and Policies, Federal Communications Commission

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Reply Comments of SkyVision Solutions

Submitted November 1, 2013

Introduction

1. Kit T. Weaver (or SkyVision Solutions) submits these “reply” comments in response to the publication of FCC 13-39, First Report and Order, Further Notice of Proposed Rule Making and Notice of Inquiry (ET Docket No. 13-84 and ET Docket No. 03-137) released March 29, 2013, by the FCC and published in the Federal Register on June 4, 2013.
2. SkyVision Solutions previously submitted comments on August 31, 2013, and “reply” comments on October 23, 2013.
3. These “reply” comments are intended to address certain comments submitted to the FCC for its Notice of Inquiry (NOI) by the Telecommunications Industry Association (TIA) comments dated September 3, 2013.
4. Summary of “Reply” Comments Provided on this Date, November 1, 2013
 - A. A phrase presented by the TIA in its comments is analyzed, i.e., *“epidemiological studies to date give no consistent or convincing evidence of a causal relation to RF exposure and any adverse health effect.”*
 - B. Epidemiological studies are important in evaluating adverse effects, but human case studies, animal studies, and in-vitro studies are also crucial in forming a complete picture of the possible health effects caused from exposure to RF radiation.
 - C. Use of the terms consistent and convincing evidence by organizations such as the TIA need to be treated with a fair amount of skepticism. With the type and amount of collective evidence available in the published literature, it is quite possible for one to objectively conclude that the hypothesis (or universal statement) that adverse health effects can be only be caused through a thermal mechanism has been falsified. Consequently, any person making claims that consistent or convincing evidence does not exist for RF emissions causing adverse health effects should be treated with skepticism and questioned as to possible bias. Additionally, it is inappropriate to accuse scientists who engage in the scientific process of falsification as “cherry picking.” On the contrary, those who suppress available scientific literature which identify adverse health effects attributed to exposure to RF radiation are those who are engaging in the practice of cherry picking.

- D. There is a possible parsing of words in claims made by such organizations as the TIA, the IEEE, and the ICNIRP when they claim adverse health effects have not been proven. Possibly they are secretly admitting that weak RF fields cause “health effects” but not necessarily “adverse health effects.” The scientific community, including the ICNIRP, IEEE, and the FCC should be more open about acknowledging that biological effects do result from exposure to weak RF emissions. Once this admission occurs, a more intelligent discussion can proceed regarding which biological effects should be considered “adverse” and which effects are benign, reversible, or non-pathological.
- E. A causal relation is one in which there is a direct relation between one event (A) and another event (B), where A precedes B and causes B. Causality can be difficult to prove with certainty. The FCC uses a “bright line” approach to exposure standards which may not be in the best interests of protecting public health and safety in cases where a credible threat from RF exposure exists but which cannot be proven with 100% certainty. Using the Bradford Hill criteria for assessing causality, it is asserted that a “causal link” can be established, based upon existing published literature, i.e., that RF exposure from wireless devices can cause adverse health effects. This assertion does not have to be proven with certainty to establish this causal link; one will take actions in proportion to the strength of the argument. It is shown that the concept of a precautionary approach is the modern or contemporary version of the application of Hill’s criteria for causation.
- F. The current FCC exposure guidelines are based upon an antiquated limit system that only recognizes biological effects that occur as a result of a thermal mechanism. FCC exposure guidelines provide no protection against non-thermal related exposures and certainly no margin of safety. It is quite rational to provide protection against consistently observed biological effects at non-thermal levels, whether it be as a part of a precautionary approach or as actions determined as warranted based upon a follow-up to a review of the Bradford Hill criteria for causation.
- G. It is a positive development within the telecommunications industry over the past several years that the power output for modern cellular phones has dropped substantially through such mechanisms as adaptive power control (implemented in order to preserve battery strength). However, many of the devices to be used in the future will not necessarily be powered by batteries. It is therefore imperative that wireless smart meters and smart appliances installed for home use be provided with mechanisms that allow the consumer to deactivate such RF transmitters.

5. Reply to TIA Comments, page 3, Harmonization

- A. The TIA states that the FCC should “globally harmonize its exposure standard.” Use of such “global” terminology ignores the fact that approximately 40% of the world’s population is governed by radiofrequency exposure limits and guidelines that are more stringent than those of the United States (based upon the exposure standards of Russia, China, India, and numerous other smaller countries). In fact, based upon the IARC declaration that RF radiation is a *possible carcinogen*, scientific evidence, and increased use of the precautionary approach, a strong argument can be made that any harmonization should be in the direction of more stringent exposure standards. Instead, the TIA only mentions organizations such as the IEEE and ICNIRP as the possible sources of “global harmonization,” essentially setting up a straw man argument in favor of less restrictive exposure standards.
- B. The TIA quotes a number of organizations that essentially do not recognize or refuse to recognize that adverse biological effects can occur from exposure to RF radiation through other than a thermal mechanism. One principal quotation by the TIA is from the ICNIRP which states that “**epidemiological studies to date give no consistent or convincing evidence of a causal relation to RF exposure and any adverse health effect.**”

At this time it is appropriate to examine the implications of specific words used in the ICNIRP quotation and the limitations of that statement:

Epidemiological Studies

Epidemiological studies are important in evaluating adverse effects, but human case studies, animal studies, and in-vitro studies are also crucial in forming a complete picture of the possible health effects caused from exposure to RF radiation. Each type of study has its limitations, but reliance totally on epidemiological studies is inappropriate given the range of possible health effects and the potential ramifications if no action is taken in response to the exponential increase of wireless devices in our society and the commensurate RF exposures.

Epidemiological studies are low sensitivity in nature, generally only look for the adverse health effect of cancer, and can take decades of study to account for latency periods for different types of cancers. In addition, epidemiological studies, because of their data collection over a period of years, are subject to such issues as recollection errors, that is, dependent on how often a person may have remembered using a cellular phone some years ago and whether that person may also have used a cordless phone that might not be accounted for in the results of the study.

Consistent and Convincing Evidence

Use of the terms consistent and convincing evidence by organizations such as the TIA need to be treated with a fair amount of skepticism. Too often, biased individuals and organizations use such words in the formulation of excuses to not properly weigh all evidence presented before them, excluding evidence that does not fully comport with established norms and beliefs. Consistent and convincing are among words that may be called the C-words. Credible and conclusive are two other words commonly used by those rejecting the premise that RF radiation can cause adverse health effects. However, the greater point here is that when organizations such as the TIA and the IEEE reject evidence that weak RF radiation fields may cause adverse health effects, they do so at the peril of also rejecting the sound scientific principle of falsification. Using Wikipedia as a basic information source at http://en.wikipedia.org/wiki/Scientific_method, the scientific method involves a process of investigating phenomenon and acquiring knowledge through a reasoned approach.

“The scientific method is the process by which science is carried out. Because science builds on previous knowledge, it consistently improves our understanding of the world. The scientific method also improves itself in the same way, meaning that it gradually becomes more effective at generating new knowledge. For example, the concept of falsification (first proposed in 1934) reduces confirmation bias by formalizing the attempt to *disprove* hypotheses rather than prove them.”

Although opponents of more stringent RF exposure standards will selectively cite elements of the scientific method such as replication of results and peer review of results published in what they deem as reputable journals, the equally valid principle of falsification or falsifiability is rarely if ever mentioned by those same individuals. Proponents of the existing FCC exposure guidelines or the IEEE standards set themselves up for a huge fall by insisting that adverse biological effects are only possible or plausible through thermally induced mechanisms. The concept of falsification is typically described through an illustration that involves a hypothesis that "All swans are white." Based upon observational data, it is possible to disprove this hypothesis by finding a single black swan, i.e., deductive logic admits the conclusion that the statement that all swans are white is false. Individuals who systematically review all available literature on the subject of RF exposure effects and compile documents such as the BioInitiative Report 2012 are following an acceptable scientific

approach. Authors of the BioInitiative Report, for example, are basically scientists reviewing all available literature looking for “black swans,” and since it would only take one credible “black swan” to put into serious question the entire FCC exposure guidelines framework, it would appear that those invested in maintaining the current limits or actually making such limits less restrictive have a lot to lose by admitting any evidence that “black swans” exist.

Furthermore, it is inappropriate to accuse scientists who engage in the scientific process of falsification as “cherry picking.” On the contrary, those who suppress available scientific literature which identify adverse health effects which may be caused by exposure to RF radiation emissions are those who are engaging in the cherry picking.

So in the context of RF emissions, do “black swans” exist? Certainly the authors of the BioInitiative Report would appear to believe so. Hundreds if not thousands of studies have shown positive results related to exposure from relatively weak RF fields. Other individuals have submitted documentation on many of these studies as part of this NOI comment process. For purposes of this “reply” comment letter, and for summary purposes, I will quote two reputable information sources:

- “Although it has been argued that RF radiation cannot induce physiological effects at exposure intensities that do not cause an increase in tissue temperature, it is likely that not all mechanisms of interaction between weak RF-EMF (with the various signal modulations used in wireless communications) and biological structures have been discovered or fully characterized. Biological systems are complex and factors such as metabolic activity, growth phase, cell density, and antioxidant level might alter the potential effects of RF radiation. Alternative mechanisms will need to be considered and explored to explain consistently observed RF dependent changes in controlled studies of biological exposure.” [emphasis added] [Reference: IARC Monograph, Volume 102, for non-ionizing radiation (and radiofrequency electromagnetic fields), published April 2013, page 104.]
- “The expert appraisal nevertheless shows, with limited levels of evidence, different biological effects in humans or animals, some of which had already been reported in 2009: these can affect sleep, male fertility or cognitive performance.” [emphasis added] [Reference: French ANSES “Update of the Radiofrequencies and Health Expert Appraisal,” Press Kit, October 15, 2013, page 2.]

With the type and amount of evidence available in the published literature, it is quite possible for one to objectively conclude that the hypothesis (or universal statement) that adverse health effects can only be caused through a thermal mechanism has been falsified. Consequently, and in summary, any person making claims that consistent or convincing evidence does not exist for RF emissions causing adverse health effects should be treated with skepticism and questioned as to possible bias.

Adverse Health Effects

There is also a possible parsing of words in claims made by such organizations as the TIA, the IEEE, and the ICNIRP when they claim that adverse health effects have not been proven. Possibly they are secretly admitting that weak RF fields cause “health effects” but not necessarily “adverse health effects.” In fact, the IARC and ANSES quotations referenced above mentioned “consistently observed RF dependent changes” and “limited levels of evidence [of] different biological effects in humans or animals.” Thus, one could surmise that conclusions are being made that observed biological effects caused by weak RF fields are not necessarily “adverse.” Of course, with the French press release, effects were noted that related to sleep, male fertility or cognitive performance. These would appear to be “adverse effects” but yet you never know how biased individuals interested in promoting the exponential and profitable use of wireless technologies in our society might twist the interpretation of the words “adverse effects.” This concept requires additional discussion.

Although there are those scientists and other individuals who promote more stringent RF exposure standards based upon documented adverse biological effects (which may not receive universal acknowledgment), there are also those who merely have a different philosophy on how governments should protect public health and safety. For instance, as documented in an [article](#)* detailing a review of the rationale for the Russian RF exposure standards, it would appear to be acknowledged that Russian scientists have in fact observed a number of biological changes in animal studies due to relatively weak RF exposure over the years. “While the USSR and Russian standards were based on many areas of research, the immunology studies were viewed by the standards committees as providing the most consistent results and so were important for setting exposure limits.” In attempting to briefly summarize the article, it will be stated that the Russian standards appear to be primarily based upon a number of experiments with animals such as rabbits, rats, guinea pigs, and mice where sub-thermal RF radiation exposures under controlled conditions prompted a number of biological responses.

[Selected quotations are provided from “Scientific Basis for the Soviet and Russian Radiofrequency Standards for the General Public,” Repacholi, et. al., 2012, *Bioelectromagnetics*, 33: 623–633.]

Regarding public health standards, “conclusions [were] as follows: chronic daily exposure to 100–500 $\mu\text{W}/\text{cm}^2$ can induce persistent pathological reactions (based on the immunology studies...), the most striking effect being offspring death after injection of foreign serum; [at approximately] 50 $\mu\text{W}/\text{cm}^2$ is the threshold exposure for the unfavorable biological effects found in the immunology studies but these effects were not pathological since the organism could compensate for the exposure, and continual compensation could lead to long-term adverse effects and thus should be protected against; and chronic exposure to $\leq 10\text{--}20$ $\mu\text{W}/\text{cm}^2$ does not induce any noticeable biological changes in small laboratory animals.”

Regarding mobile phone standards, “Because mobile phones have become an essential part of most people’s lives, the RNCNIRP decided that they needed a special standard, especially since their use involves daily, repeated, and potentially life-long RF exposure to the brain, a critical organ.” As an example, “When rats and mice of different ages were exposed to 970 MHz fields as low as 15 $\mu\text{W}/\text{cm}^2$ for up to 120 min there was a tendency toward a decrease in exploratory behavior, a suppression of the righting reflex, and a slowdown in adaption to experimental conditions. In addition, a fourfold decrease in noradrenaline levels was observed in exposed animals compared to the control group. ... When determining the limit values for mobile telecommunications technology, the RNCNIRP decided to leave the limit value of 10 $\mu\text{W}/\text{cm}^2$ for the general public unchanged, as it was set in 1984 and this value was well justified by previous research so there was no need for change. Thus, base stations should not expose the public to more than 10 $\mu\text{W}/\text{cm}^2$.” For mobile phone users, a limit value of 100 $\mu\text{W}/\text{cm}^2$ was recommended. This limit provided a safety factor of 5 as compared to “earlier studies indicating that exposure to 500 $\mu\text{W}/\text{cm}^2$ produced immune system changes considered pathogenic to the organism.” [Russian Standard, 2003].

“The general approach to public health protection and setting exposure limits by previous Soviet and current Russian committees is that people should not have to compensate for any effects produced by RF exposure, even though they are not shown to be adverse to health (pathological). In other words, these committees assume there could be long-term health consequences if people have to compensate for RF exposures that produce biological but not pathological effects. Exposure limits are then set that do not cause any possible biological

consequence among the population (regardless of age or gender) that could be detected by modern methods during the RF exposure period or long after it has finished. Their approach to protection is that limits of RF exposure should not cause even a temporary initiation of the protective or adaptive compensatory mechanisms over the near or long term. Thus, the final exposure limits are set as a fraction of the minimum RF exposure that is capable of provoking some adaptation-compensatory reactions in people.”

“Children are not small adults since they are developing organisms with special sensitivities and might be expected to be more sensitive to EMF than adults [Grigoriev, 2005; Kheifets et al., 2005]. Thus, results of studies conducted on adults might not be validly extrapolated to children; therefore, the RNCNIRP considered that children need special consideration when developing exposure limits. According to the RNCNIRP, the following health hazards are likely to be faced in the near future by children who use mobile phones: disruption of memory, decline in attention, diminished learning and cognitive abilities, increased irritability, sleep problems, increase in sensitivity to stress, and increased epileptic readiness. For these reasons, special recommendations on child safety from mobile phones have been incorporated into the current Russian mobile phone standard [Russian Standard, 2003].”

“The various USSR and Russian standards committees considered that chronic exposure to nonthermal levels of RF fields was potentially hazardous to human health. Further, the key philosophy used to set limit values in the Russian standards was that RF exposure should not produce any effect that had to be compensated for by people because it was believed that this would lead to pathologic effects over the long term [Grigoriev et al., 2003b,c].”

So to summarize with regard to Russian exposure guidelines, they are developed with the recognition that non-thermal effects do occur and these effects have been documented. It is not stated with certainty that all observed effects are pathological and/or irreversible, but in any case, it is concluded that such effects influence the physical and mental well being of affected individuals and therefore constitute a health hazard. The Russian guidelines, therefore, are science-based but include an aspect of the precautionary principle in that the guidelines are intended to prevent pathological effects that are considered plausible and possibly even likely if exposure at elevated levels were allowed to occur on a long-term basis.

The scientific community, including the ICNIRP, IEEE, and the FCC should be more open about acknowledging that biological effects do result from exposure to weak RF emissions. Once this admission

occurs, a more intelligent discussion can proceed regarding which biological effects should be considered “adverse” and which effects are benign, reversible, or non-pathological.

Causal Relation

Now to discuss what it means to have a causal relation between RF exposure and adverse health effects. In general terms, a causal relation is one in which there is a direct relation between one event (A) and another event (B), where A precedes B and causes B. Causality can be difficult to prove. The FCC uses a “bright line” approach to developing exposure standards which may not be in the best interests of protecting public health and safety in cases where a credible threat from RF exposure exists but which cannot be proven with 100% certainty. Accordingly, SkyVision Solutions has recommended (in prior comments) that a precautionary approach to limiting RF exposures be implemented until such time that more appropriate biologically based limits can be developed.

This portion of the “reply” comments letter is intended to document how “causality” need not be a rigid “bright line” issue and that causality fits nicely into a regulatory framework that includes a precautionary approach to help protect public health and safety.

The American Academy of Environmental Medicine (AAEM) has issued a position paper on the topic of “Electromagnetic and Radiofrequency Fields Effect on Human Health” available for viewing at the following link: http://aaemonline.org/emf_rf_position.html. In this paper the AAEM states: “Because of the well documented studies showing adverse effects on health and the not fully understood quantum field effect, AAEM calls for exercising precaution with regard to EMF, RF and general frequency exposure. In an era when all society relies on the benefits of electronics, we must find ideas and technologies that do not disturb bodily function. It is clear that the human body uses electricity from the chemical bond to the nerve impulse and obviously this orderly sequence can be disturbed by an individual-specific electromagnetic frequency environment.” In this referenced position paper, the AAEM makes what to some is a controversial statement that “many *in vitro*, *in vivo* and epidemiological studies demonstrate that significant harmful biological effects occur from non-thermal RF exposure and satisfy Hill’s criteria of **causality**.” [emphasis added]

As the AAEM position paper was issued to address possible concerns over wide-spread deployment of wireless smart meters, in the timeframe of April 2012, the Michigan Public Service Commission

(MPSC) asked the Smart Grid Technical Advisory Project at the Lawrence Berkeley National Laboratory (LBNL) to review the AAEM position paper submitted to the MPSC as part of the Docket for Case U-17000. It is noted that the “Smart Grid Technical Advisory Project” has as one of its objectives to “Provide technical assistance and facilitation services to assist state regulatory commissions and policymakers better understand near-term smart grid implementation and policy issues.” Based upon available information, it is evident that activities of this group are funded through a US DOE Energy Smart Grid Investment Grant. As such, it is expected that individuals who performed the review of the AAEM position paper may reasonably be considered advocates of smart meter deployments. That said, the review conducted by the LBNL “Smart Grid Technical Advisory Project” primarily focused on the issue of whether the AAEM could reasonably claim that Hill’s criteria of causality is satisfied for RF radiation non-thermal exposure effects. Before proceeding further with the LBNL “Smart Grid Technical Advisory Project” review, SkyVision Solutions will provide a summary of “Hill’s criteria.”

In 1965, Sir Austin Bradford Hill detailed nine criteria for assessing evidence of causation, sometimes referred to as “Hill’s criteria,” which may be used to extend research from one area to other related areas.

[Reference: Hill, Austin Bradford, “The Environment and Disease: Association or Causation?”, *Proceedings of the Royal Society of Medicine*, 1965, volume 58, pp 295-300.]

The article attempts to answer the question of, “In what circumstances can we pass from [an] observed *association* to a verdict of *causation*?” In some sense, Hill’s criteria may be viewed as a management tool or mental process by which to methodically assess whether an association (or possible link) between an environmental agent and disease can be determined to be a matter of cause and effect. The nine parameters for association are:

- 1) Strength. An example is given in the article that supports a likely strong link between smokers of cigarettes and the number of deaths due to lung cancer. At the same time, Hill states, “In thus putting emphasis upon the strength of an association we must, nevertheless, look at the obverse of the coin. We must not be too ready to dismiss a cause-and-effect hypothesis merely on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so. Relatively few persons harboring the meningococcus fall sick of meningococcal meningitis.”

- 2) Consistency. “Has it been repeatedly observed by different persons, in different places, circumstances and times?” An example used (again in 1965) is that “Returning to my more general example, the Advisory Committee to the Surgeon-General of the United States Public Health Service found the association of smoking with cancer of the lung in 29 retrospective and 7 prospective inquiries.” ... “In other words we can justifiably infer that the association is not due to some constant error or fallacy that permeates every inquiry.” ... “Once again looking at the obverse of the coin there will be occasions when repetition is absent or impossible and yet we should not hesitate to draw conclusions.”
- 3) Specificity. “If, as here, the association is limited to specific workers and to particular sites and types of disease and there is no association between the work and other modes of dying, then clearly that is a strong argument in favor of causation.” ... “In short, if specificity exists we may be able to draw conclusions without hesitation; if it is not apparent, we are not thereby necessarily left sitting irresolutely on the fence.”
- 4) Temporality. Does the cause precede the effect? “My fourth characteristic is the temporal relationship of the association – which is the cart and which the horse?” ... “This temporal problem may not arise often but it certainly needs to be remembered, particularly with selective factors at work in industry.”
- 5) Biological Gradient. “Fifthly, if the association is one which can reveal a biological gradient, or dose-response curve, then we should look most carefully for such evidence. For instance, the fact that the death rate from cancer of the lung rises linearly with the number of cigarettes smoked daily, adds a very great deal to the simpler evidence that cigarette smokers have a higher death rate than non-smokers.” ... “Often the difficulty is to secure some satisfactory quantitative measure of the environment which will permit us to explore this dose-response. But we should invariably seek it.”
- 6) Plausibility. “It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day.” ... “In short, the association we observe may be one new to science or medicine and we must not dismiss it too light-heartedly as just too odd. As Sherlock Holmes advised Dr Watson, 'when you have

eliminated the impossible, whatever remains, however improbable, must be the truth.”

- 7) Coherence. “On the other hand the cause-and effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease - in the expression of the Advisory Committee to the Surgeon - General it should have coherence. Thus in the discussion of lung cancer the Committee finds its association with cigarette smoking coherent with the temporal rise that has taken place in the two variables over the last generation and with the sex difference in mortality...”
- 8) Experiment. Are there clinical studies supporting the association? In addition, and referencing back to the tobacco cases, if people stop smoking, do death rates from lung cancer fall? We now know that it does.
- 9) Analogy. Is the observed association supported by similar associations? “In some circumstances it would be fair to judge by analogy. With the effects of thalidomide and rubella before us we would surely be ready to accept slighter but similar evidence with another drug or another viral disease in pregnancy.”

Some of Sir Hill’s final statements in the article were:

- “None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question - is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?”
- “Finally, in passing from association to causation I believe in 'real life' we shall have to consider what flows from that decision. On scientific grounds we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it - or who hangs because of it. But in another and more practical sense we may surely ask what is involved in our decision. In occupational medicine our object is usually to take action. If this be operative cause and that be deleterious effect, then we shall wish to intervene to abolish or reduce death or disease.”

- “While that is a commendable ambition it almost inevitably leads us to introduce differential standards before we convict. Thus on relatively slight evidence we might decide to restrict the use of a drug for early-morning sickness in pregnant women. If we are wrong in deducing causation from association no great harm will be done. The good lady and the pharmaceutical industry will doubtless survive.” [emphasis added]
- “But we should need very strong evidence before we made people burn a fuel in their homes that they do not like or ... stop eating the fats and sugar that they do like.”

In summary, the “Hill criteria” offer a quite practical thought process by which to help determine whether a suspected link between an environmental agent and a specific set of symptoms or disease can further be determined to be a cause-and-effect relationship. The AAEM asserts that such a relationship exists for RF emissions, but it is clear that a certain amount of clinical judgment is used in making that determination. Such judgment makes use of both subjective and objective data. In addition, insight provided by Sir Hill within the published article reveals that different practical decisions may be made depending on the level of evidence and the costs of taking action. Sir Hill states that in “real life,” decisions will be made based upon the “differential standards.” This explanation has the effect of the modern day concept of “prudent avoidance” or use of the “precautionary approach” in dealing with credible cause-and-effect relationships.

In a [letter](#) dated, April 18, 2012, two members of the Smart Grid Technical Advisory Project, Lawrence Berkeley National Laboratory, wrote a letter addressed to the Michigan Public Service Commission (in response to an MPSC request of a few days earlier). The letter focused on listing Hill’s criteria in a more simplistic form than described above and then attempted to apply the criteria to RF exposure emissions from both cell phones and smart meters. Let it be clear that the LBNL limited review was an exercise where the authors attempted to demonstrate that there was insufficient evidence to show causality of adverse effects for smart meters. The remarkable aspect about the LBNL review is that it provided a reasonable tabulation (possibly inadvertently) that would lead one to conclude that several criterion of the Hill criteria could be considered met for cell phones to at least some degree. For example, for cell phones, the LBNL review indicated that there was “limited evidence” for consistency based upon the INTERPHONE study; possible “oxidative stress markers and pathological changes in brain tissue” for specificity; some “well controlled lab studies” show a cause preceding an effect for temporality; there is “limited coherence”; there is experimental

evidence where “some studies suggesting reported effects”; and there is a “presumed” analogy with “earlier (generally higher power) microwave studies.” An excerpt from the table contained in the LBNL letter is provided below.

Hill Criteria Applied to RF Emissions from Cell Phone Radiation as Possible Agent to Cause Adverse Health Effects	
Hill Criteria	Cell phones
Strength: How large is the effect?	No widespread disease has yet been reported.
Consistency: Has the same association been observed by others, in different populations, using a different method?	Limited evidence from INTERPHONE study, interpreted differently by different researchers.
Specificity: Does altering only the cause alter the effect?	A variety of studies have looked at changes in experimental setup to alter the source or size of the exposure with compelling results, most of which are related to distinct endpoints (e.g. oxidative stress markers and pathological changes in brain tissue in AAEM citation 16)
Temporality: Does the cause precede the effect?	Hard to discern in some epidemiology studies because hard to know state of individuals prior to study. Generally well controlled in lab studies.
Biological gradient: Is there a dose response?	Intensity of fields is often assumed as dose in a thermal model. For non-thermal effects, these criteria may not apply until we have a better understanding of dose.
Plausibility: Does it make sense? (Hill noted that knowledge of the mechanism is limited by current knowledge).	Mechanisms have not been well developed other than heating processes, where it is assumed that energy accumulates until dissipated.
Coherence: Does the evidence fit with what is known regarding the natural history and biology of the outcome?	Limited coherence – many of the reported effects have unknown etiologies.
Experiment: Are there any clinical studies supporting the association?	There are some studies suggesting effects under certain circumstances.
Analogy: Is the observed association supported by similar associations?	Presumed to be supported by earlier (generally higher power) microwave studies.

Source: Excerpt from Table from page 2 of April 18, 2012, Letter from Smart Grid Technical Advisory Group, LBNL to Michigan PSC

For wireless smart meters, the major conclusion for the LBNL review was “No published, peer-reviewed scientific research at this time” for basically eight of the nine criteria. The overall conclusion of this review was, “It is instructive to use this framework to consider the available evidence: based on our judgment, **the Hill’s criteria have not been satisfied for smart meters, regardless of how well they may or may not be satisfied for cell phones.**” [emphasis added].

Without attempting to address the smart meter issues as a part of this “reply” comment letter, SkyVision Solutions asserts that the April 2012 “Smart Grid Technical Advisory Project” review offered a somewhat simplistic review of the Hill’s criteria as applied to cell phones. Nevertheless, and using Hill’s criteria, the LBNL review actually helped substantiate the AAEM claim, at least for cell phones, that adverse biological effects occur based upon exposure to non-thermal RF exposure.

In the prior written comments, evidence was presented that a precautionary approach was warranted for limiting future exposure to radiofrequency (RF) radiation emissions from wireless devices. As was shown, the precautionary approach is a concept that analyzing a situation to evaluate whether human activities may lead to ***unacceptable harm*** that is scientifically ***plausible*** but uncertain. If such harm is shown to be scientifically plausible, then actions should be taken to avoid or diminish that harm. Additionally, precautionary measures should be chosen that are proportional to the seriousness of the potential harm.

Bradford Hill himself insisted that what he was proposing was not a check list where all the boxes have to be ticked. In any real situation, some of the criteria may not be met. For example, there is no dose response when you take a drug overdose: you either die or you don’t. What is deemed “plausible” can also change over time. In the nineteenth century it was thought totally implausible that doctors not washing their hands could be responsible for the deaths of women in maternity wards. But the criteria do suggest the sorts of questions we should ask when we are faced with a *prima facie* case for hazard and we are trying to decide whether action is warranted. It is thus asserted that a “causal link” can be established, based upon existing published literature, that RF exposure from wireless devices can cause adverse health effects. It does not have to be proven with certainty to establish this causal link; one will take actions in proportion to the strength of the argument. It is also clear that precautionary approach concept is the modern or contemporary version of the application of Hill’s criteria for causation.

Although SkyVision Solutions will not elaborate further on the topic of causation with regard to RF emissions from wireless devices based upon personal research, it is the understanding of SkyVision Solutions that a new published article will be released within a few days of these “reply” comments having been filed, entitled, “RF-EMF Emissions from Wireless Phones Are Class 1 Human Carcinogens.” Reportedly, the abstract for this article by Hardell, et.al, will state:

“Using the long-established and respected Bradford Hill criteria for assessing causality, this paper shows that RF-EMF exposure from mobile (and cordless) phones should be regarded as an IARC class 1 human carcinogen (cancel causing agent). Current guidelines for exposure need to be urgently revised.

Current guidelines for exposure need to be urgently revised. Wireless phones, i.e. mobile phones and cordless phones, emit radiofrequency electromagnetic fields (RF-EMF) when used. An increased risk of brain tumors is a major concern. The International Agency for Research on Cancer (IARC) at the World Health Organization (WHO) evaluated the carcinogenic effect to humans from RF-EMF in May 2011. It was concluded that RF-EMF is a group 2B, i.e. a ‘possible’, human carcinogen.

Bradford Hill gave a presidential address at the British Royal Society of Medicine in 1965 on the association or causation that provides a helpful framework for evaluation of the brain tumour risk from RF-EMF.

All nine issues on causation according to Hill were evaluated. Regarding wireless phones, only studies with long-term use were included. In addition, laboratory studies and data on the incidence of brain tumours were considered.

The criteria on strength, consistency, specificity, temporality, and biologic gradient for evidence of increased risk for glioma and acoustic neuroma were fulfilled.

Additional evidence came from plausibility and analogy based on laboratory studies.

Regarding coherence, several studies show increasing incidence of brain tumours, especially in the most exposed area. Support for the experiment came from antioxidants that can alleviate the generation of reactive oxygen species involved in biologic effects, although a direct mechanism for brain tumor carcinogenesis has

not been shown. In addition, the finding of no increased risk for brain tumors in subjects using the mobile phone only in a car with an external antenna is supportive evidence. Hill did not consider it was essential, or even very likely, that all the listed criteria were likely to be fulfilled.”

SkyVision Solutions has confirmed with the Editor-in-Chief of *Reviews on Environmental Health* that the subject article will be available soon and should be available through the following link:

<http://www.degruyter.com/view/j/reveh?rskey=AC6Lwt&result=1>.

6. TIA Comments, page 9, Exposure Standards Protecting All Populations

- A. The TIA states that “Additional precautionary measures are not needed. In the present case, the standards already provide for a substantial margin between the exposure limits and the levels where any health effects have been observed. This substantial margin inarguably constitutes a more than sufficient precaution. It is sufficient to protect all members of the public at large, including seniors and children. Given the current safety margins, there is no scientific rationale for additional safety margin—it simply is not needed.”
- B. Based upon evidence presented by SkyVision Solutions, the above statement is completely without merit. It is indisputable that non-thermal related RF emissions from wireless devices cause health effects that can be observed. The current FCC exposure guidelines are based upon an antiquated limit system that only recognizes biological effects that occur as a result of a thermal mechanism, essentially treating the human organism as a piece of meat to be heated in a microwave oven. FCC exposure guidelines provide no protection against non-thermal RF exposure levels and certainly no margin of safety. As has been previously stated, what remains as a legitimate debate is to discuss what extent observed biological effects caused by exposure to weak RF radiation are pathological and/or irreversible. In addition, it is quite rational to provide protection against observed biological effects at non-thermal levels, whether it be as a part of a precautionary approach or as actions determined as warranted based upon a follow-up to a review of the Bradford Hill criteria for causation.

7. TIA Comments, page 20, Technical Approach to Addressing Exposure Reductions

- A. The TIA states that one reason that additional technical approaches are not necessary for reducing RF exposures is that “due to market effects that result from manufacturers striving for further battery life

than their competitors, exposure reduction is occurring as newer RF-emitting [information and communications technology] ICT products evolve to meet consumer needs.”

- B. It is a positive development within the telecommunications industry over the past several years that power output for modern cellular phones has dropped substantially through such mechanisms as adaptive power control (implemented in order to preserve battery strength). However, many of the RF emitting devices to be used in the future will not necessarily be powered by batteries. As documented in previously submitted comments, it is imperative that wireless smart meters and smart appliances installed for home use be provided with mechanisms that allow the consumer to deactivate such RF transmitters. Otherwise, as shown below by a smart grid industry supplied image, homes could eventually be saturated with RF emissions from possibly every appliance in the home, what to some individuals would be viewed as a microwave nightmare scenario.

