

From: Art Barondes [mailto:abarondes@erols.com] **On Behalf Of** art.barondes@analyticsint.com
Sent: Monday, August 14, 2006 6:07 PM
To: Beck, Nancy
Subject: Proposed Risk Assessment Bulletin

Dear Dr. Beck

I realize that your time for comment has passed and I do not want to unduly “muddy your waters” on this subject, but I offer these two comments for whatever you think they are worth...

1. Your Bulletin indicates that it is applicable to the Executive Branch (item XI, p. 26), but I would offer that there are major Risk Assessment stakeholders in the Legislative and Judicial Branches. It would be helpful if all branches could be on the “same sheet of music.” As you are probably well aware, the congress, building on the Clean Air Act (1970), has come close to legislating a standardized approach to risk assessment (e.g., S.981 “Levin Bill,” 1998). Then, too, the courts have become increasingly involved in the nature and validity of risk assessments. Some applicable cases over the past 60 years include:
 - a. *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947): Judge Hand developed the “Hand formula” where a party has acted “unreasonably” [the legal standard for negligent conduct] when the burden taken for precaution (B) is less than the probability that a particular harm will materialize (P) times that harm’s magnitude (L), i.e., if $B < PL$, the party is negligent. The Hand formula is predominantly a qualitative tool in tort cases because of difficulties in quantifying terms.
 - b. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, Nos. 82-524; -545; -551 (U.S. June 6, 1983): At issue was a determination by the Nuclear Regulatory Commission (NRC), in the face of great scientific uncertainty, that storage of high-level nuclear wastes would have no significant environmental impact. The Court of Appeals, by a divided panel, concluded the rules were arbitrary and capricious and inconsistent with National Environmental Policy Act (NEPA) because the NRC had not considered the uncertainties. The Supreme Court reversed the D.C. Circuit’s decision ruling. The NRC acknowledged the zero-release assumption was surrounded with uncertainty. The Court pointed out that the “zero-release assumption” was developed for the limited purpose of considering risks of the most likely long-term waste disposal method. Further, uncertainties concerning the zero-release assumption were offset by conservative assumptions in other values.
 - c. *Daubert v. Merrill Dow Pharmaceuticals* (1993) required that uncertainty be treated explicitly in presenting scientific testimony and required peer review to lend some credence to testimony.
 - d. *Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA* (1998), the courts actually delved into risk assessment methodologies to consider completeness and evaluate validity.
2. The Department of Defense—the largest agency in the Executive Branch—seems to be tacitly and uniquely excluded. The 14 June 2006 submission from the G48 System Safety Committee (WB1) of the Government Electronics and Information Technology Association (GEIA) supports this view with the statement, “It does not appear that the risk assessment work done under MIL-STD-882 [“Standard Practice For System Safety”] is within this scope.” This exclusion can pose major problems in that MIL-STD-882 is a far cry from the scientific approach advocated in the

Bulletin and supported by essentially all of the non-DoD risk assessment community including the Legislative and Judicial Branches.

My credentials: I've been in the probabilistic risk assessment (PRA) business for major weapon systems for the past 15 years addressing predominantly DoD risks of plutonium dispersal from nuclear weapons and risks from conventional explosives.

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