I. INTRODUCTION/BACKGROUND - draft #3

A. CURRENT ETHICAL REGUIREMENTS

Every Federal employee is bound by the code of ethics passed by Congress on June 27, 1980 and signed by the President on July, 1980 (1). The code sets forth general principles of behavior to which all Federal employees should adhere. They are to remind employees that the public has entrusted to them important responsibilities for spending tax dollars and for seeing that these dollars are not wasted, misused, or diverted for private gain. Some of these reponsibilities have been codified into criminal and civil laws, and they contain measures for punishing violations. Most federal agencies have their own regulations spelling out in detail how these laws apply to their employees.

The Environmental Protection Agency (EPA) has instituted regulations entitled: "Standards of Conduct..." (2). Curiously, the object of these regulations is limited to concerns for bribery, theft and conflict of interest, where individuals generally stand to receive immediate monetary rewards. The possibilities of the theft of ideas, scientific fraud, or misrepresenting information for political purposes seem to have been overlooked. This oversight may have great consequences for an Agency with such an all encompassing mission as protecting public health and the environment. Scientific fraud at EPA could, for example, coverup knowledge of a cancer causing substance in a major food source, or prevent an epidemiological study from exposing the fact people are being poisoned from an important industrial source of pollution. Political appointees could accomplish these to prevent a publi outcry. One only has to look, however, at the now famous NASA shuttle disaster to see the terrible consequences of putting public relations ahead of critical technical information.

The fact that ethical misconduct in a regulatory agency can have very serious consequences for public health and/or the environment should be obvious. It should also be obvious that the principles for designing, conducting and evaluating scientific and technical information, as well as how this information can be ethically used, needs to be understood by those who work in such programs - professionals as well as managers. And, given the nature of human beings, there also needs to be a real threat of punishment for those who seek to ignore ethical principles.

B. ETHICAL CONCERNS IN EPA DECISIONMAKING

In June of 1983, William Ruckelshaus gave an important speech to the National Academy of Sciences explaining that EPA had implemented a recommendation of NAS to separate the two functions of risk assessment and risk management(3). Mr. Ruckelshaus said this after having just returned to start his second tenure as EPA Administrator. He returned to an EPA underfire for, among other things, allowing politics to influence scientific work. Indeed, one scientist had resigned over an ethical issue; he was requested to alter his findings to fit a political decision. Other questionable practices were surfacing in the news, and it was necessary to alter the growing public perception that EPA was not protecting them.

Ruckelshaus' policy was an attempt at separating the political decisions from the scientific decisions by placing them in different locations in the organization. The principle of the action was admirable because, as Mr. Ruckelshaus stated:

> "...risk assessment at EPA must be based on scientific evidence and scientific consensus only. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the asessment of risk."

He apparently assumed that once separated, science would operate ethically and be immune from political influence, even though political appointees would be incharge of both areas. Adding political influence to the already known difficulties in maintaining professional ethics was not understood to create problems. This is not to say that the distinction made by Mr. Ruckelshaus was not useful. On the contrary, it was an idea that started EPA professionals considering where "policy considerations" were influencing their work.

As a result of their deliberations, EPA professionals have recently proposed a code of professional ethics designed to identify problem areas and resolve them. This was accomplished by the professional union at EPA, The National Federation of Federal Employees (NFFE) Local 2050, as part of their continuing dialogue with Agency management over ways to improve the professional work environment at EPA and achieve the mission of the Agency. The union proposal identifies the major areas where ethical misconduct can take place in regulatory decisionmaking, how to identify violations and a mechanism for bringing about resolution. The essence of this agreement is summarized in Figure 1.

C. FLUORIDE IN DRINKING WATER - A CASE STUDY

The single most important factor in the decision to propose a code of ethics by the union was the decision by EPA in November of 1986 to double the amount of fluoride in drinking water considered to be safe (Recommended Maximum Contaminant Level) and double the legally allowable level of fluoride in drinking water (the Maximum Contaminant Level). During the early stages of proposing the new regulations, the union heard a complaint from a professional in the Office of Drinking Water, that the decision was scientifically unsupportable. Members of the executive board of the union then began an investigation. They found numerous areas of apparent ethical misconduct from the scientific investigations themselves to the subsequent decision documents. The union made numerous attempts in meetings and in writing to alert EPA top management to their findings, but to no avail. Calls for a review by the union were ignored as were requests for seminars to have the contractor defend their analysis before appropriate EPA professionals.

The union appealed to the Science Advisory Board (SAB) who refused to get involved claiming that there was insufficient time in which to do an adquate review before the planned date of publication in the Federal Register. The regulation was subsequently published and NRDC promptly sued in the U.S. Court of Appeals for the District of Columbia. Having attempted internal appeals and failed, the union asked the court (Judges R. Ginsberg, J. Buckley, and W. Bork) for permission to file an amicus brief. This was denied without comment and the intended brief was returned to the union. None of the information presented in the brief was entered in the record. All three judges ruled against NRDC, deferring to the expertise of the Agency. This decision was double ironic considering the fact that the Agency's experts - the professionals - had attempted to oppose the Agency in court. The regulation now stands as written.

D. PURPOSE OF THIS PAPER

The process by which the fluoride regulation was developed illustrates some of the many ethical problems associated with regulatory science. The authors, who have an accumulated 34 years experience in a professional capacity in regulatory programs believe that an open debate on this subject is long overdue. We attempt in this paper to lay out the ethical minefiled inherent in EPA's decisionmaking process and how ethical principles can be violated by using one program in EPA and one particularly egregious example of unethical behavior- the fluoride in drinking water regulations.

By the time this paper is published, there may be an agreement with the Agency on a code of ethics. This should provide the proper mechanism for evaluating how the fluoride regulation was developed and for taking appropriate action. In our opinion, the possibility of a positive finding of scientific fraud is very high and the Agency will need to examine the implications for public health.

II. ETHICAL FRAMEWORK FOR EVALUATING REGULATORY DECISIONMAKING

A. ENSURING PROPER INTERPRETATION OF THE LAW.

1. Law and congressional intent.

- The purpose of the law and congressional intent needs to be understood by those involved in carrying it out. The Executive Branch is not free to ignore Congress.

2. Agency discretion.

- Judges will avoid reviewing cases where there are questions about the interpretation of technical issues. They differ instead to the agencies. Where before agencies had a narrow area of discretion, they can now broaden it to include almost anything they want if they keep issues technical.
- There needs to be internal review of technical issues by professionals free of political interference.

3. The role of the Professional and the Administrator.

- Assessment of legal, scientific and technical information is the responsibility of the professional. Their analyses are not discretionary.
- Professionals must use the best principles, knowledge and techniques of their particular discipline for the achievement of the mission of the Agency.
- The Administrator's job is to ensure that expert professional personnel are hired and given the necessary resources to get the job done and to see that the process by which scientific and technical decisions are made is carried out properly.
- Decisions requiring the weighing of the social and economic impact of regulatory options is the responsibility of the Administrator, who must be consistent with the law.

B. ENSURING SCIENTIFIC CREDIBILITY.

1. Scope of work.

- The nature of the job must be defined and the resources necessary for completion must be ascertained.

2. Literature review.

- A risk assessment requires a reivew of the primary literature from the world's literature.
- Normal rules for accepting or rejecting literature apply. Conflicting data and opinions about the meaning of scientific data must be explained or the conclusion left to future research.

3. Secondary sources.

- The selection of secondary sources must not be biased and be up to date.

4. Defining terms, questions, and assumptions.
- As a result of the first review of literature, terms are identified which need explanation, questions come up which need answering, and assumptions that will be used in evaluting the information need to be identified. If secondary sources become suspect, they must then be reviewed and even the orginial literature reviewed if necessary.

5. Representing facts, depth of analysis and areas of uncertainty.
- It goes without saying that honesty requires accurately representing facts, the depth of the analysis and areas of uncertainty.
- "Trimming, cooking and forging of data" are as reprehensible in professional work in government as they are in the scientific and technical communitities.
- There is plenty of room for "Differing Professional Opinion" as long as the opinions are grounded in the requirements of the law.

6. Preventing preconceived conclusions from entering process.
- The entire process of scientific and technical assessment needs to separated from the pressures which come from the area of politics.
- Assessments need to be published separate and appart from decsions which have elements of discretion based on social and economic impacts.

7. Ensuring professionalism and essential government functions.
- Decisions as to the health implications of data must be retained by government professionals who are sworn to uphold the public's interest.
- Project managers must become experts in technical arguments presented by assessent.
- Technical reviewers must have expertise in their particular discipline.

8. Public comment.
- Drafts for public comment must be honestly open to criticism and the results of comments incorporated so that quality comes first and meeting deadlines is secondary. Imposition of deadlines should result in honest assessments of quality and their public health impact.

9. Completing final document.
- Final document should stand on its own, having been reviewed by peers both inside and outside the government.
- There should be no check for political acceptability.

C. DEVELOPING STAFF AMD PROGRAM TO CARRY OUT THE LAW

1. Selection of project manager and asssessment team.
- Job of risk assessment requires a professional who is capable of understanding scientific and technical issues and who can work with specialists.
- Assessment team need to be discipline experts who can evaluate data gathered by contractors.

2. Defining goal.
- Requirements of the law are a framework to develop the scope of the work that needs to be done.

3. Developing program.
- Written work plans identifying issues and time frames need to be developed and constantly refined as answers to questions are found and information needs identified.

4. Use of contractors.
- Contractors should be used to gather raw data, in a systematic way. The meaning of that data can only be interpreted by a government professional who is sworn to uphold the public's trust.

5. Internal and external review procedures.
- A peer review procedure needs to be instituted in EPA. Current "program review" does not suffice.
- Public comment of documents that have undergone internal peer review should be sufficient to obtain

III. ETHICAL ISSUES IN THE DECISION TO RAISE THE RMCL AND MCL FOR FLUORIDE IN DRINKING WATER.

A. INTERPRETATION OF THE LAW

1. REQUIREMENTS OF 1976 SAFE DRINKING WATER ACT

a. primary standards:RMCL/MCL

- There is no necessity for RMCL to be the same as MCL. Fear of publicly pointing out toxicity of fluoride pushed Agency to set RMCL=MCL.

b. secondary standard

- EPA created new reason for secondary standard by declaring fluorosis a cosmetic effect.

c. timing

- 1976 law set interim standards requiring EPA to set final standards. EPA decided not to follow the law until forced to by court suit.

2. LEVEL OF CERTAINTY REQUIRED
- Language of law and record clearly requires that the drinking water standards be preventative. Only need to make a "may present" a risk case, not a totally conclusive one as EPA suggests.

3. DEGREE OF PROTECTION REQUIRED
   a. per cent of population
- Law requires that everyone be protected, not just majority or even 95% but <u>all</u> people. Many EPA statements suggest not everyone need be protected.

   b. susceptible individuals
- Law requires that weaker members of society be protected, not just healthy ones as suggested by EPA.

   c. margin of safety
- Law requires a margin of safety. Even for health effects that EPA was willing to admit existed, there was no margin of safety.

4. AUTHORITY FOR MAKING SCIENTIFIC JUDGEMENTS
- The Administrator, who is incapable of making scientific judgements, somehow rejected expert opinion.

B. SCIENTIFIC CREDIBILITY
1. Lack of final report.
2. Lack of expertise in preparation of report.
3. Misuse of contractors.
4. Crippling Skeletal fluorosis
   a. Misrepresentation of 20 mg/day threshold
      i. Ignored health effects at earlier stages.
      ii. Ignored workers who were more sensitive.
      iii. Ignored fact that workers were <u>adults</u>.
      iv.
4. Failure to define terms, ask proper questions and state assumptions.
5.

1. SCIENTIFIC TASK PRESENTED BY LAW
- As noted above, scientists were supposed to identify the health effects that were likely to occur. By ignoring possible effects and requiring absolute proof, numerous effects that probably occur were

The Safe Drinking Water Act requires that EPA determine what harmful effects are likely to occur - not shown conclusively as suggested by EPA.

2. LITERATURE REVIEW
3. AUTHORITY OF SOURCES, USE OF SECONDARY SOURCES
4. DEFINITION OF TERMS, QUESTIONS, AND ASSUMPTIONS
5. PRESENTATION OF FACTS, DEPTH OF ANALYSIS AND AREAS OF UNCERTAINTY
6. ROLE OF POLITICAL INFLUENCE
7. ENSURING INTEGRITY OF PEER REVIEW PROCESS.
8. PUBLIC COMMENT
9. COMPLETING FINAL DOCUMENT