



International Guidance Activities

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My charge today is to review international guidance activities on principles for setting Protective Action Guides (PAGs). It's really quite a simple task. There is only one set of guidance in existence now; that guidance is currently under revision; and we don't have the results yet. The principal group involved in generating this guidance is the International Commission on Radiation Protection (ICRP). Contributing groups include the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA) -- which represents the European Community, primarily, and is part of the Organization for Economic Cooperation and Development (OECD). In the case of PAGs for food, there are some complicating factors; other agencies enter the picture -- the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the Codex Alimentarius have been mentioned several times today. Skip Engel discussed that subset of considerations in an earlier paper. Here, instead of those more complex issues, we will focus on the basic principles upon which all PAGs are based.

We need a common set of basic principles because we need to get to the bottom line (PAGs) in an unequivocal way that everybody understands. Let me give you an example of how equivocal some international organizations have been, on this question of PAGs, in the recent past. An unnamed international health agency, just a very few years ago, right after Chernobyl, set out to produce PAGs. They stated their intentions as two objectives. The first was: ". . . to set [Protective Action Guides], below which the introduction of control measures cannot be justified on the grounds of protecting health." But, they went on to recognize, control measures could still be introduced for other reasons, as health is not the sole criterion for decisionmaking. This first part of their objectives can be paraphrased as, "We will set a level below which you don't need to do anything, but you might do something anyway." The second objective was, "The [PAGs] will represent levels above which control measures should be considered, but not necessarily introduced." I would paraphrase this as saying: "We will set a level above which you should consider doing something, but you might do nothing anyway." I don't know how anybody could derive decisive action based on that set of objectives.

International principles for setting PAGs are contained in two key documents that contain identical statements. One is Publication Number 40 of the ICRP, which was issued in 1985. The title is "Protection of the Public in the Event of Major Radiation Accidents, Principles for

Planning." The other is the IAEA's Safety Series Publication Number 72, also issued in 1985, written by many of the same authors and titled, "Principles for Establishing Intervention Levels."

The principles that were set forth in these documents were identical, were incomplete, and they are, unfortunately, the only principles that are now in effect, while proposed revisions go through one draft after another. There are several such draft revisions that are of significance. The most important is that of the ICRP. The basic guidance that applies to most planned exposure to radiation is ICRP Publication 26. That document has been under revision by the Commission for a number of years, and the new version will, for the first time, include recommendations for emergency response. They are now getting close to closure, and I think it should be a very much improved and useful document. But it isn't finished yet.

Such guidance doesn't get developed in a vacuum, and there have been a couple of parallel efforts which have provided significant input to the ICRP, which is essentially a behind-closed-doors effort. These other efforts are more open. One of these is being carried out within the IAEA, which has convened annual meetings of national experts for a number of years in Vienna, to generate a replacement for Safety Series No. 72, mentioned earlier. There is a meeting scheduled this December to complete this effort; and, hopefully, we will reach closure at that meeting on at least the basic principles.

The Nuclear Energy Agency (NEA) has also been at work. It has convened a group of experts from member nations that have been developing recommendations. There is an overlap between the ICRP, the IAEA, and the NEA groups, and they are all headed in the same direction. By this time next year, with luck we will have international agreement on the basic principles, and both the ICRP and the IAEA will have published their new reports.

With that as a preamble, we can move to the principles themselves. These are shown in Figure 1, which lists the basic considerations for selecting PAGs. What should we expect the set of principles to say? It is fairly obvious, I think. First, avoid unreasonable risks of acute and long-term health effects. Next, avoid additional health risk when it is cost effective to do so; and finally, the risk from the protective action must be less than the radiation risk avoided. You certainly do not want to do anything which causes more harm than good.

Figure 1

Basis for Selecting PAGs

- Avoid unreasonable risks of:
 - Acute health effects
 - Long-term health effects, and
- Avoid additional health risks when it is cost-effective to do so; but,
- The risk from the protective action must be less than the radiation risk avoided.

In a little more sophisticated formulation, the NEA, in its review of the principles for deriving PAGs, has put together a chart showing their basic objectives. This is given in Figure 2, and shows how the ICRP 26 principles for normal situations translate into the accident situation. This transition from principles for normal situations is something, by the way, that has been resisted for a long time; the tendency has been to treat accidents as unique. Under ICRP 26 -- that is, for normal radiation protection when you have a source that is under control and you are really deciding how much control you want to exercise -- there are three principles. They are called justification, optimization, and limitation (or constraints on individual risk). Justification is something which has usually already taken place before radiation protection people get involved -- like the decision to have nuclear power or not. Optimization is, basically, making the choice of the best buy for the money in control. It's what we call ALARA. The optimization process results in regulations like 40 CFR 190, the 25-millirem EPA standard that the nuclear industry operates under for normal releases. We all know the dose limits for limitation of individual risk. They are well established. The dose limits referred to here are the overall limits; for example, in the United States it is our 500 millirem Federal Radiation Protection Guide.

Figure 2

NEA

(April, 1989)

	<u>Normal case</u> <u>Source under control</u>	<u>Accident</u> <u>Source out of control</u>
Justification	Justification of a practice	Justification of a protective measure
Optimization	Choice of the "best" option for control	Choice of the "right" intervention level
Constraints on total individual risk	Dose limits for workers and for the public	Radiological risk and risk from protective measures kept below unacceptable levels

Now, when you consider the accident situation, some interesting changes take place. You're no longer justifying the practice -- the existence of the source -- what you are justifying is the imposition of a protective measure. The source is already there. So the justification requirement becomes much more real. It's the determination that taking the protective action will do you some good. Optimization really remains the same -- it's a question of where you get the greatest protection for the effort, including the cost. But there is a subtle difference. In the case of a source that is being controlled, you are usually looking at a discrete set of control options, e.g. what type of control of iodine releases do you install, or how much holdup of noble gases. Whereas, in the case of protective action you are really looking at the choice of the level

of radiation exposure at which you introduce the protective action. This is a continuous range, not a set of discrete options.

Finally, we must consider constraints on total individual risk. In the normal case, specified dose limits exist, e.g. the ICRP's current dose limits are 100 millirems for chronic exposure, and 500 millirems for non-recurring planned exposures. In the case of an accident, there are no numbers. In the international guidance under development, that will remain the case. What will emerge is a recognition that individual countries will have to make decisions about what level of protection they want to provide people, as an upper bound to risk under accident situations. But, it is not something on which numerical international guidance will be offered.

Figure 3 shows the existing international principles, as they have been set down in ICRP-40. It is kind of a mess, really. The first principle is an example of limitation; it corresponds to the third principle on Figure 2. It is an upper limit on risk, but it only applies to nonstochastic effects. That is, there is no recognition of the need to provide an upper bound on health effects from stochastic effects in the existing international guidance. That is one of the things that needs to be fixed.

Figure 3

ICRP 40

Principles for planning intervention in the event of an accident:

- (a) **Serious nonstochastic effects should be avoided by the introduction of countermeasures to limit individual dose to levels below the thresholds for these effects.**
- (b) **The risk from stochastic effects should be limited by introducing countermeasures which achieve a positive net benefit to the individuals exposed.**

This can be accomplished by comparing the reduction in individual dose, and therefore individual risk, that would follow the introduction of a countermeasure with the increase in individual risk resulting from the introduction that countermeasure.

- (c) **The overall incidence of stochastic effects should be limited, as far as reasonably practicable, by reducing the collective dose equivalent.**

This source-related assessment may be carried out by cost benefit analysis techniques and would be similar to a process of optimization in that the cost of a decrease in the health detriment in the affected population is balanced against the cost of further countermeasures.

The second principle in ICRP-40 is the most difficult one to analyze. It actually is a requirement for justification of a protective action. What it really says is, "Don't do it if it isn't going to do more good than harm." The word "stochastic" is misleading here, because it implies that stochastic effects have been limited. They have not. This is a justification requirement, but not well expressed because it leaves out the costs implied by the protective action. And finally, the last principle is expressed correctly. It is a requirement for optimization, or ALARA. It is the only one that is expressed clearly and completely in the existing guidance.

Figure 4 shows last year's draft of new principles prepared by an expert group for the IAEA. It is much clearer. There are three principles: justification, optimization, and limitation of the risk to individuals. The third principle adds to the old ICRP-40 statement the phrase "the level of total radiation exposure of individuals should be maintained below that which is regarded as unacceptable for stochastic effects . . ." This level is not defined, and it's left to each country to decide what it's going to do.

Figure 4

IAEA DRAFT REVISION OF PUBLICATION 72 (11/88)

PRINCIPLES FOR ESTABLISHING INTERVENTION LEVELS

Intervention should be justified (i.e. the particular action should do more good than harm for the group of people it will affect).

The protection of the population should be optimized (i.e. the particular action should be implemented at the level which will produce the most good).

The risks to individuals should be constrained below unacceptable levels (i.e. the level of total radiation exposure to individuals should be maintained below that which is regarded as unacceptable for stochastic effects, and below that which serious non-stochastic health effects could occur).

Figure 5 shows what EPA has done in its revised draft revision of the PAG manual; it is essentially identical to the principles in Figure 4. We have tried to choose words that would be clearer. The first two principles here deal with the limitation of risk to individuals; they deal separately with nonstochastic and stochastic effects. They should be considered together as limitation of individual risk. The third principle is a requirement for ALARA, and the fourth one is a requirement that the protective action be justified, i.e., that it do more good than harm.

Figure 5

EPA

(April, 1989)

1. Acute effects on health (those that would be observable within a short period of time and which have a dose threshold below which such effects are not likely to occur) should be avoided.
2. The risk of delayed effects on health (primarily cancer and genetic effects for which linear nonthreshold relationships to dose are assumed) should not exceed upper bounds that are judged to be adequately protective of public health under emergency conditions, and are reasonably achievable.
3. PAGs should not be higher than justified on the basis of optimization of cost and the collective risk of effects on health. That is, any reduction of risk to public health avoidable at acceptable cost should be carried out.
4. Regardless of the above principles, the risk to health from a protective action should not itself exceed the risk to health from the dose that would be avoided.

This summarizes the current state of advice on how to set PAGs. I would like to make two additional points. One minor and one major. The minor one is that none of these sets of principles requires that the PAGs be expressed in terms of rems, or sieverts. They may be expressed in terms of any kind of indicator of exposure that is useful for deciding when to introduce a protective action. The second, and major point, is that I think we really need a fourth principle to be added to the three we have been discussing. That is to keep PAGs as simple as possible. This is essential so that political decision makers can go about the vital business of providing protection of the public without having to make complicated radiological health judgements that it is unreasonable to assume they are trained to carry out.