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Docketing and Service Branch
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

To whom it may concern:

Enclosed please find our comments on the Commission's policy statement on Below Regulatory Concern (BRC) published in the Federal Register of July 3, 1990 (55 FR 27522-37). We are writing in response to your request for comments published July 23 in the Federal Register (55 FR 29925-6).

John Greenberg

Educati · the Public in Clean Alternatives to Nuclear Power

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The Great "Below Regulatory Concern" Hoax: Deregulation is Bad for You, But You'll Learn to Like It

After years of deliberation, the Nuclear Regulatory Commission has finally issued its "below regulatory concern" policy statement. The policy itself has no basis in law, fact, or logic. The policy statement is a veritable casebook of invalid reasoning. The policy conclusions are a recipe for environmental disaster.

Is There Any Legal Basis for This Policy?

Our constitutional system of government gives to Congress the right to pass certain laws, and to regulatory agencies the right to establish the regulations to enforce them. It is a government of limited powers, strictly separated and balanced in order to prevent any organ of government from overpowering any other. The Constitution does not give the Courts the right to write legislation, nor the Congress the right to try cases. Each body in our government must function within the strict limitations of the Constitution, which, in the 9th Amendment explicitly states that "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

When any agency or organization exceeds its power, it acts without the Constitutional authority necessary to make its statements or policies enforceable. Its actions are, in the legal jargon, ultra vires, that is, beyond the power of the agency to enforce. Such actions are, in short, unconstitutional and indefensible seizures of power. The Courts cannot enforce them; the Executive cannot carry them out.

This is precisely the case here. There is no question that the Congress of the United States asked the Nuclear Regulatory Commission to formulate a policy concerning materials to be considered "below regulatory concern," but the mandate granted was specific and precise. This policy not only goes beyond the mandate; it flatly and openly contradicts it. It is a naked assault on the Constitutional notion of limited powers.

In the Low Level Radioactive Waste Policy Amendments Act of 1985, Congress addressed the pressing problem of what it termed "low-level" radioactive waste. In Section 10 of that act, Congress requires the Commission to "establish standards and procedures ... for considering and acting upon petitions to exempt specific radioactive waste streams from regulation...". The law, however, also clarifies this chore, by defining the rationale on which such standards should be established: namely, whether or not regulation is "necessary to protect the public health and safety...".

No other rationale is given, and this is significant. For example, the law does not suggest that standards could be set at levels which endanger public health and safety to any extent, no matter how small, in order to achieve a significant savings in cost. A close reading of this section shows that Congress did not intend that radioactive wastes be exempted from regulation, unless a showing is made that the public health and safety are not

endangered. Period.[1]

The legislative history of the Low Level Radioactive Waste Policy Amendments Act of 1985 only underscores the point we are making. In pertinent part, it reads: "The NRC should exercise such authority with particular care and diligence to ensure that waste that may be a possible threat to public health and safety does not escape careful regulation."[2]

The Commission's path therefore is clear. Its job, in relation to this mandate from Congress, is to limit itself to a technical consideration of waste materials, exempting only those which are of "sufficiently low concentrations or quantities" as to be not injurious to the protection of "the public health and safety." Moreover, the law does not assert that there are any such concentrations or quantities; it merely requires the Commission to search them out and define them.

The Commission has explicitly chosen to adopt the no-threshold hypothesis of dose damage,[3] which, in simple laymen's language states that there is no safe dose of radiation. The Policy Statement makes this unequivocally clear on page 7: "It is important to emphasize that, in this policy, the Commission does not assert an absence or threshold of risk at low radiation dose levels ...".[4] The Commission has therefore, quite properly we think, and with elegant simplicity, fulfilled the mandate Congress set before it, which was to search out and define a health threshold.

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1. The Commission quotes its legal directive in the Low Level Radioactive Waste Policy Amendments Act of 1985 on page 3 of its policy statement, omitting both references to its basic mandate. The pertinent portion of Section 10 reads as follows (with our added italics):

> ...the Commission shall determine in an expeditious manner whether the concentration or quantity of radionuclides present in such waste stream requires regulation by the Commission *in order to protect the public health and safety*. Where the Commission determines that regulation of a radioactive waste stream is *not necessary to protect the public health and safety*, the Commission shall take such steps as may be necessary, in an expeditious manner, to exempt the disposal of such radioactive waste from regulation by the Commission."

2. House Report (Energy and Commerce Committee) No. 99-314(II), Dec. 4, 1985 [To accompany H.R. 1083] [1985 USCCAN 3026]. There is nothing in the legislative history which modifies or contradicts this fundamental point. There was no Senate report submitted with this legislation.

3. Cf., e.g., pp. 5-9 of the "Policy Statement," and p. 49888 of the Federal Register publication of the advanced notice of this "proposed statement."

4. We quote and respond to the rest of this sentence below.

Following the normal rules of logic, this should have been the end of the Commission's "below regulatory concern" policy statement. Or more precisely, the Commission should have concluded with the only possible logical inference. Since Congress asked it to declare materials below regulatory concern only "in order to protect the public health and safety," and since the Commission has emphasized that it does not assert any threshold risk for public health and safety, it can only find that there are no materials which can be found "below regulatory concern."[5]

Since the Commission has no respect for either logic or legal mandates, however, it did not stop at the obvious conclusion. Instead, invoking a variety of specious rationalizations -- "sound use of limited National resources"[6], "the need to balance incremental reductions in risk below the safety threshold with the attendant expenditure of private and public resources"[7], "the Commission's judgment on acceptable risk"[8], "the presence of natural background radiation"[9] among others -- the Commission goes far beyond the mandate both of Congress and of logic.

Before exploring the factual and logical basis for these justifications, one point should be made indisputably clear. The Commission has no authority to determine the "sound use of limited National resources." The Commission is the Nuclear Regulatory Commission, not the Council of Economic Advisors. The Commission was never asked to determine any "balance" of incremental risks and benefits. Nor was it invited to express its judgment on "acceptable" risk; Congress did that explicitly and unequivocally. The Commission was not asked to form an opinion of -- or worse still a policy statement based on -- "natural background radiation." In short, the Commission's attempt to determine national policy in these and other areas is wholly without legal basis. It is, in sum, ultra vires.

When is a Threshold Not a Threshold?: When a Risk is not a Risk

The Commission's policy is premised on a basic, explicitly stated contradiction. As already noted, the Commission emphatically denies the existence of a threshold of risk from low doses of radiation. They acknowledge that all doses are unsafe.[10] Notwithstanding this clear assertion of current-

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5. To repeat: since Congress never asserted that there are any such materials, this conclusion in no way contradicts the mandate of Congress.

6. Policy Statement, p. 2.

7. Policy Statement, p. 2.

8. Policy Statement, p. 2.

9. Policy Statement, p. 7.

10. Cf. Policy Statement, p. 7.

ly accepted scientific fact, the Commission waves its regulatory magic wand, and presto chango: "Over the last several years, the Commission has pursued the development of a risk threshold to distinguish those radioactive materials that do not require the same stringent level of regulatory control as that imposed on potentially more hazardous materials."[11]

If all radiation is hazardous, then what the Commission has really been seeking is a level of hazard which, in its unelected, unmandated wisdom, the Commission itself finds acceptable. In other words, the Commission has spent years searching for a threshold at which it can express its regulatory disdain for the health and safety of the American people.

Since this point is absolutely crucial, we do not mind belaboring it a bit. The Commission tells us -- and we heartily agree -- that radiation at any level presents a hazard to human health and safety. Equally helpfully, they suggest that they have set the threshold to correspond to "a risk of about 4 chances in 10,000 (3.5×10^{-4}) or a hypothetical increase of about 0.25% in an individual's lifetime risk of fatal cancer."[12] There is thus no question at all as to whether there is a risk involved. In fact, the same risk can be restated a bit differently. If 10,000 individuals are exposed to the level of radiation the NRC is proposing as a threshold, and if the NRC's figures are correct (a point about which considerable controversy exists), then 4 of those individuals will die from cancer directly attributable to the radiation dose. More will contract non-fatal cancers and other diseases,[13] but these are apparently beneath the Commission's 'regulatory concern:' the policy statement mentions no health effects other than fatal cancers.

In other words, the Commission has been searching for several years, not for a safety threshold, which does not exist, but for the number of corpses which it deigns to consider "acceptable." Seek and ye shall find. Having laboriously determined that 4 dead bodies in 10,000 is "acceptable," the Commission has apparently decided that 5 or more dead bodies constitutes "significant risk."

There is a frequent fallacy involved in interpreting statistical risk assessments which it is crucial to expose immediately. The Commission's con-

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11. Policy Statement, p. 2. We should point out, at least in passing, that if this policy is enforced, this last phrase "do not require the same stringent level of regulatory control" really means no level of enforcement at all.

12. Policy Statement, p. 7.

13. Cf., e.g. BIER V, p. 1: "Well demonstrated late effects include the induction of cancer, genetically determined ill-health, developmental abnormalities, and some degenerative diseases (e.g. cataracts)." Under the category of developmental abnormalities, BIER V notes in particular the clear association of fetal irradiation and mental retardation (pp. 355-362). Sterility can also be induced by irradiation (cf. p. 365-6) In general, BIER V shows clearly that fatal cancers are not the only health effect from radiation.

clusion that 4 in 10,000 people are at risk is either correct or it isn't. But if it is correct, then it means that 4 people will be affected. There is no uncertainty about this. What remains uncertain (other than the always hypothetical nature of any scientific statement) is which 4 people will be affected. Thus, the Commission is saying, in a roundabout fashion, that it finds it acceptable to kill 4 people in 10,000, as long as it doesn't know who they are. On this theory, premeditated mass murder is acceptable, as long as you don't know whom you're killing.

They Were Going to Die Anyway ...

The Commission invokes a variety of rationales in attempting to support this indefensible posture. Each is more specious than the next. For example,

> The Commission believes that if the risk from doses to individuals from a practice under consideration for exemption is comparable to other voluntary and involuntary risks which are commonly accepted by those same individuals without significant efforts to reduce them, then the level of protection from that practice should be adequate. ...[14]

This simple sounding statement reveals a morass of flawed reasoning. The logic of what the Commission is arguing comes to this. People are subjected to x amount of risk independently from the risks considered here. They "accept" those risks.[15] Therefore, they should be willing to accept x risk in our little corner: namely the question of radioactive materials. More simply, if individuals are currently accepting risk of x, then they should equally willingly accept 2x risk. This of course makes no sense at all.

The fallacy behind the Commission's logic is made still plainer in what follows. For example, the Commission states:

> Variations in natural background radiation apparently play no role in individual's decisions in common matters such as places to live or work (e.g. the 60-70 mrem differences between average annual doses received in Denver, Colorado versus Washington, DC).[16]

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14. Policy Statement, p. 7.

15. We are reminded of the reported remark of Margaret Fuller, "I accept the universe," and Thomas Carlyle's supposed retort: "My God! she'd better." Exactly what are individuals to do who do not accept "natural background radiation"?

16. Policy Statement, p.7

A few simple questions are in order. How does the Commission know whether this is or is not a factor in anyone's reasoning. Has it surveyed the populations in question? Out of the entire 250 million people in the United States, how many actually know about the difference in natural background radiation? Of those, how many know what such a difference might imply for human health? What other factors actually entered into the decisions to live in the places in question? Assuming such decisions were made on strictly rational bases, what other factors would a rational person consider about each of these environments? After all, no one has ever asserted that radiation is the only risk to human health and safety. Since we are confident that the Commission has not asked these questions, let alone answered them, we are equally confident that the Commission's statement is a gratuitous, self-serving surmise.

Precisely the same can be said for the next excuse:

> In addition, individuals generally do not seem to be concerned about the difference in doses between living in a brick house versus a frame house, the 5 mrem dose received during a typical roundtrip coast-to-coast flight, or incremental doses from other activities that fall well within common variations in background radiation.[17]

All of the same questions apply here. Again, the Commission is simply shooting from the hip.

Using these indefensible premises, the Commission arrives at its conclusion:

> These factors lead to the conclusion that the differential rate risks corresponding to doses on the order of 5-10 mrem (0.05-0.1 mSv) are well within the range of doses that are commonly accepted by members of the public, and that this is an appropriate order of magnitude for the Commission's BRC individual dose criterion.[18]

Nothing is adduced here or elsewhere to provide a reasonable basis for the notion that any dose is "accepted" by the public, assuming that the word "accept" implies a voluntary choice. Besides, it is remarkable that an agency charged with regulating a complex technical field would claim to base its decisions on what is "commonly accepted by members of the public." While the Commission has not one scintilla of evidence to support the claim, we are now to believe that if "individuals generally" "seem" to "feel" that a given level

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17. Policy statement, p. 7.

18. Policy statement, p. 7.

of risk is acceptable, then by golly, it must be acceptable.[19] Presto chango. There's that magic wand again.

Costs vs. Benefits: Where's the Beef?

Surely a policy so clearly designed to put human beings (not to mention other life forms) at risk must have enormous benefits to compensate for demanding the ultimate sacrifice of randomly exposed members of the public at large. In a society which purports to be humane and civilized, we have grown accustomed to believe that human life is to be sacrificed only for essential benefit, otherwise unobtainable.

In lieu of any actual benefits, the Commission does attempt to provide some excuses for this policy. Essentially, there seem to be three of them, all really quite intertwined. The Commission is concerned about "the associated burdens" of "additional regulation" beyond the "adequate protection threshold."[20] There is no attempt to spell out what these burdens might be, but the Commission explicitly rejects any notion that a "net societal benefit" has been in any way calculated or considered:

> The Commission believes that justification decisions involving social and cultural value judgements should be made by affected elements of society[21] and not the regulatory agency. Consequently, the Commission will not consider whether a practice is justified in terms of net societal benefits.[22]

Thus, what the right hand giveth, the left hand taketh away: yet again. The Commission expresses its concern about "the associated burdens" of "additional regulation," but since these explicitly exclude any question of "net societal benefits," we are left with no clear indication of just what the burdens might be.

There is, of course, the obvious suspicion that the Commission's concern

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19. Should health agencies decide to follow the reasoning used here, they would have to conclude that smoking is not dangerous to human health, since, at least until recently, it was "commonly accepted by members of the public."

20. Policy Statement, p. 3. Cf., also, page 6: "The costs of the controls that could be imposed for further dose reduction are not balanced by the potential commensurate reduction in risk."

21. These "elements," however, exclude states, localities, or members of the public, all of whom will be preempted by this policy statement, assuming the view of the Commission's majority prevails. It is thus less than clear exactly who the NRC believes will or should make this decision.

22. Policy Statement, p. 6.

here is the profit margin of private operators.[23] It is probably true that the Commission is weighing costs to nuclear operators against the lives of those for whom nuclear materials are regulated, though this is never stated quite so baldly. Our experience with the Commission over the past twenty years makes this more than a blind stab on our part, however.

There being no contraindications, we can also assume that the calculation has been made naively. We can guess that the Commission's calculation runs simply thus: if we deregulate materials in this quantity and in these concentrations, the nuclear industry will be able to forego costs amounting to $X. Thus, $X is the "the associated burdens" of "additional regulation."

We call this calculation naive because it fails to consider not only cultural and social costs, but even offsetting economic costs. Thus, no attempt has been made to calculate the costs of treatment for fatal and non-fatal cancer, or other health effects of the increased radiation burden. No effort has been made to determine what effects -- even strictly economic effects -- will ensue from the public's knowledge that "ordinary" landfills will contain radioactive waste if this policy is enacted. This country is in the midst of a serious solid waste crisis, which we can expect to be effected by this policy in a wide variety of ways, both economic and otherwise. We can assume that no attempt has been made to net out the cost savings to the generators, who will in most cases still have to meet the rising cost of disposing of even "ordinary" garbage.

In short, we can assume that the Commission's analysis of the economic issues provides an excellent indication of precisely why its authority is and should be limited to non-economic matters. Of course, our examination of the Commission's views on the subject has necessarily had to be performed strictly by "guesstimate." The Commission has chosen to remain silent on the exact nature of this supposed benefit of its policy.

The commissioners are more forthcoming in stating explicitly and repeatedly that the policy will, if enacted, save the Commission's own resources. For example, they state:

> To require that all radioactive materials be controlled in the same strict manner regardless of the risks they pose would not be a sound use of limited National resources.[24]

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23. The Commission does couch this concern, at various points, in terms of, e.g., "increased assurance that funds available to decommission operating nuclear facilities will be adequate." (p.1) It never mentions any alternative way of providing this "increased assurance," such as, for example, seeing to it that the generators set aside sufficient funds during their operating years. Nor is there any comparison of the risks and benefits of this and other alternatives to the policy.

24. Policy Statement, p 2.

Now if this policy statement makes one thing clear, it shows that the Commission is very concerned about putting things in perspective. The radiation risk that will kill 4 individuals in 10,000 is compared in the statement to "natural background radiation," living in Denver, living in a brick house, and a variety of other non-relevant phenomena, all in an attempt to minimize the importance of the risk. Of course, since human life is involved here, these are all odious comparisons.

When it comes to matters of money, however, the Commission suddenly becomes quite reticent: no comparisons are forthcoming. We, however, are not so timid, nor is there any appropriate reason to be reticent. The NRC's entire budget has been on the order of 450 million dollars in the last few years. During the same period, the nation's resources (gross national product) have amounted to between 4500 and 5500 billion dollars, and the total federal budget has hovered around 1000 billion dollars. Thus, the NRC's entire budget is .04% of the whole federal budget, and somewhere between .007 and .009% of the nation's economic resources. Clearly, the Commission is not going to save its entire budget by adopting this policy. It therefore goes without saying that these percentages, however small, represent an extreme exaggeration of the amounts that could potentially be saved by this policy. In fact, the percentages are at least one and probably closer to two orders of magnitude too high.[25]

The Commission adduces one other supposed benefit of this policy, and refers to it repeatedly:

> The Commission is concerned that inconsistent regulation of BRC wastes could result in differing levels of risks to the public and the environment through the application of different residual radioactive criteria in the cleanup of contaminated sites. The Commission is also concerned that inconsistent regulation of BRC waste could in fact undermine State and Federal efforts to manage low-level waste safely.[26]

Two points are pertinent here. The first is obvious: consistency can be achieved by lowering the threshold of risk just as easily as it can by raising it. A BRC policy which states that all radiation is dangerous and that there is therefore no threshold of risk (or more precisely, that the threshold is set at zero) is just as consistent as any other policy. The second point is only slightly less clear: there is no obvious connection between consistency and safety. A policy which sets too high a threshold -- like this one for

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25. It is worth noting, however, that the Commission makes no attempt to calculate, estimate or in any way place a dollar figure on the amount of the Nation's limited resources that they intend to save by killing randomly chosen American citizens.

26. Policy statement, p. 4

example -- is consistently unsafe.

Surveying the alleged advantages of the proposed policy, we are left with none that withstands close scrutiny. All of the benefits alleged by the NRC can be achieved in other ways, none of which is examined in this policy statement. Net economic costs may well weigh against the adoption of this policy: until a proper analysis is performed, no one will ever know. The Nation's resources are certainly not so limited as to be incapable of bearing the expenses of regulation which are in question here. In fact, these expenses are vanishingly small when viewed against the totality of the nation's resources. Finally, consistency can be achieved at safe dose levels just as easily as it can at the dangerous ones proposed here.

Another point should be weighed in measuring any supposed benefits against the admitted risks of this policy. The class of people who enjoy any benefits from this policy is not the same class as those who will be forced to undergo the risks. No one has alleged, for example, that there are any future benefits to be obtained from this policy, but since radionuclides remain hazardous for many years, there will be risks from this policy long into the future. If an isotope with a hazardous life of, say, 1,000 years escapes into the biosphere, it will harm anyone who comes in contact with it during that whole period, not just those of us living today. Similarly, many of those living today will undergo the risks associated with increased environmental radiation without enjoying any associated benefits.

In a similar vein, it should be noted that most of those harmed by radiation undergo this risk involuntarily: the individuals taking the risks did not choose to do so. This is clearly true of future people contaminated by radionuclides created or emitted at present. It is often true of the present population as well. By contrast, most of the other risks to which this risk is compared are accepted voluntarily: the person taking the risk also receives the benefits.

The Last Word

The Commission is well beyond its mandate in promulgating this policy; in fact, it has no legal authority to implement it. Despite some attempted sleight of hand, the proposed policy does entail explicit, substantive risk to the public; these risks are not balanced by any compensating benefits. More precisely, the implementation of the policy will result in loss of human (and other) life, with no gain to society or to any but the most narrowly defined interests of a select group of individuals. This policy of random premeditated murder has no place in civilized society. It is unconscionable.

John Greenberg
September 6, 1990

A contractor study was initiated in 1987 and is scheduled for completion by early 1991 (as shown in Enclosure 5). The staff will consider whether further modifications to § 20.303 are appropriate at that time.

Another regulation governing effluents, Part 50, Appendix I, was developed as a generic ALARA regulation. Although technology may be somewhat improved since the original analysis, no major flaw has appeared in the original basis for these ALARA criteria. Therefore, the staff does not believe that these criteria should be reexamined further.

The second step to be undertaken is to systematically assess the doses for each exemption. This task will be accomplished with contractor assistance. In those cases where the exemption results in doses that exceed the individual and/or collective dose criteria of the policy, a cost-benefit analysis will be performed to determine whether the doses resulting from the exemption are ALARA. After these dose estimates and subsequent analyses are completed, the staff will be in a position to determine which exemption regulations are candidates for revision in order to achieve consistency with the policy. Examination of the principal literature on previous estimates of doses from specific exemptions has been initiated. Existing dose estimates, if judged adequate, could be the basis for determining that the dose criteria of the policy are unlikely to be exceeded. Also, existing analyses may provide at least a partial basis for decisions on whether ALARA is met for exemptions exceeding the dose criteria. However, for consistency, dose estimation should be conducted as uniformly as practical with a consistent, up-to-date model and modeling assumptions. As indicated in Enclosure 5, the preliminary schedule for completion of the assessment of existing exemptions is September 1993; however, this depends on the number and complexity of the ALARA analyses needed.

Activity (3)(b) will involve the rulemaking actions necessary to revise exemptions for consistency with the policy statement. The number and extent of these rulemaking actions cannot be precisely determined until the systematic assessment has been completed. However, preliminary reviews suggest that at least six rulemakings are likely to be needed. The effort necessary to conduct these rulemakings is included in the staff's resource estimate. Any other rulemaking actions determined to be necessary as a result of the systematic assessment will require additional resources in the period 1993 and beyond. The order of the six rulemakings discussed below is not meant as an indication of their priorities.

One rulemaking that has been identified by the preliminary review as a candidate for conforming the regulations to the policy would be reducing the specific individual dose criterion in 10 CFR § 32.28 applicable to gas and aerosol detectors (smoke detectors) from 5 mrem/year to 1 mrem/year. The 5 mrem/year criterion was part of the initial rulemaking for smoke detectors in 1969 and was compatible with the developing industry's practice for the quantities of Am-241 used per detector at the time. As a result of advancements in the design of smoke detectors and the issuance in 1977 of the internationally accepted Nuclear Energy Agency (NEA) smoke detector standard with its recommended limit of 1 microcurie of Am-241 per detector, manufacturers are generally making smoke detectors which meet the 1 mrem/year criterion. Given the present situation, an ALARA analysis would not support the continued use of a 5 mrem/year criterion. Thus a rather straightforward rulemaking would make this regulation consistent with the interim criterion for practices involving widespread distribution of materials in the policy statement. It would preclude unnecessary ~~increases in~~ doses in the future and would ~~also~~ be ~~generally more~~ consistent with the international regulatory community.

The second rulemaking that would appear to be necessary to conform the regulations to the policy is a revision of 10 CFR Part 40, "Domestic Licensing of Source Material," to upgrade the ~~safety~~ requirements and to improve tracking of exemptions by the Commission. The staff has been aware for a number of years that such a rulemaking is desirable. In addition to updating the ~~safety~~ requirements for the source material exemptions, revision of the rule would appear to be critical to the ability of the Commission to monitor the effectiveness of the policy and maintain total exposures from multiple sources within the appropriate limit. A rulemaking to revise 10 CFR Part 40 ~~would probably~~ involve revamping the regulation to make it more consistent with the approach taken in 10 CFR Part 30 for the regulation of byproduct material and ~~should~~ consider other aspects of source material licensing beyond the exemptions. Concerning the source material exemptions in Part 40, requirements similar to those applicable to the distribution of materials and products exempt from licensing under Part 30, such as quality assurance, ~~should~~ be considered. Better controls and information on distribution of source materials to unrestricted use may be especially important to the Commission's stated intent to control "multiple" exposures since the consumer products previously estimated to produce the greatest collective exposures contain source material. Before initiating this rulemaking, a preliminary research and cost effectiveness study would be conducted to determine the most effective approach.

A third potential rulemaking that may be necessary to achieve consistency of the regulations with the policy statement would be modifications of references to an outright prohibition of the use of radioactive material in food, beverages, cosmetics, drugs, toys, adornments, or otherwise designed for ingestion, inhalation, or application to the human body. Some part of this prohibition appears at least four places in the regulations (§§ 30.14, 30.19, 32.11(c), and 32.18(b)). Although this may be a relatively simple rulemaking, it may also be controversial and raise public opposition. Also, other agencies such as the Food and Drug Administration and the Consumer Product Safety Commission may have a regulatory interest in such modifications.

Additionally, a rulemaking which should be seriously considered would be to resume annual reporting of quantities of materials and products distributed to exempt persons. Such a requirement would be in keeping with the Commission's stated intent that it will maintain cognizance over the types of exemptions granted and the quantities of material distributed under exemptions. Since 1983, reports have been required only every 5 years without the requirement to break the data down by years. This has made it difficult for the staff to maintain a clear picture of distribution trends of materials and products to exempt persons. Information of this type will be important if the NRC is to keep current on the amount of materials being released to unrestricted use and to carry out the stated intent to ensure that the exposures of the public from all sources controlled by the NRC do not exceed 100 mrem/yr. Keeping up with information on the distribution of materials on an annual basis will also be important in achieving an effective continuing public information program.

In addition to these four rulemakings, the staff believes that two rulemakings to revise the exempt quantities and exempt concentration tables of 10 CFR Part 30 will be necessary after completion of the assessment and calculation of doses based upon updated models and scientific information. However, these and other amendments and revisions to specific exemption regulations can only be initiated after completion of the review and assessment of the respective individual exemptions for consistency with the policy statement.

In addition to rule changes, there are other documents, such as regulatory guides, standard review plans, and possibly branch positions that may also need revision because of inconsistencies either with the policy itself or with the amendments made to the regulations. The staff has not yet identified all the specific revisions that might be needed and thus cannot estimate at this time what level of effort will be necessary. A somewhat lower priority will be given to these tasks. Those revisions that reflect changes to existing

regulations governing exemptions or any new guidance needed for new exemptions would be initiated after the associated rulemaking is well underway. One document that has been identified is Standard Review Plan 11.6, "Method for Obtaining Approval of Proposed Disposal Procedures," which is presently under development by NRR. This SRP addresses requests for approval under § 20.302 to dispose of licensed material in a manner not otherwise authorized in the regulations. Since NMSS, NRR, ~~NRC~~ Regional offices ~~within NRC~~, and the Agreement States can authorize these disposals, a formal review-plan with uniform criteria is needed in order to provide a consistent ~~agency~~ approach in staff evaluations. One issue to be resolved is whether BRC criteria are applicable to actions taken under § 20.302 which do not ~~retrieve disposals from possible future requirements, i.e., some actions under § 20.302 do not~~ remove materials from regulatory control. ~~A plan to deal with~~ this issue, and others related to § 20.302 disposals, is the subject of a separate Commission paper being prepared by the staff.

The remaining three areas of effort ~~of the four~~ that were specifically requested by the Commission in the October 13, 1989, SRM (activities (4) through (6)) are relatively straightforward. Resource estimates for these activities do not depend to any extent on the outcome of the systematic assessment and associated rulemaking tasks.

For activity (4), the development of guidance for the staff to ensure consistent implementation of the policy, a task force approach has been used, involving knowledgeable staff from the various offices whose work will need to incorporate the policy. Federal Register notification of rulemakings and licensing actions was distributed on July 30, 1990 (Enclosure 6). Other guidance will be developed ~~in a similar manner~~. As distinct from the development of Regulatory Guides associated with specific regulations, activity (4) is to develop generic guidance on BRC issues, e.g., criteria for defining a practice.

In regard to activity (5) concerning information dissemination, GPA has prepared and is distributing the "plain English" pamphlet on exemptions. In addition to that and other planned information dissemination, the staff has been and will continue to be responding to many letters of inquiry, including a large number of Congressional requests. Besides the written documents, the staff is actively presenting and explaining the policy in various technical, professional, and public forums. ~~This requires travel funds in addition to the staff time and effort.~~ Furthermore, the staff will maintain cognizance of efforts involved in a Committee on Interagency Radiation

Research and Policy Coordination (CIRRPC) initiative to develop a national policy on education of the public regarding the risks from radiation.

In regard to activity (6), concerning health effects research, there are currently several initiatives underway. These include examination of effects from high-LET radiation for incorporation into NUREG/CR-4214 and confirmatory research on effects of hot particles on the skin. In addition, the NRC staff participates formally in several authoritative committees and panels such as the CIRRPC Science Panel. There are also other ongoing activities, such as attending professional meetings and symposia and keeping informed about other involved agencies' activities, through which the staff currently keeps abreast of and encourages appropriate health effects research. The task called for in this plan is to review, maintain, and possibly augment the ongoing program to assure staff cognizance of health effects research and ensure that necessary research is conducted. In addition, this information will be utilized in evaluating the implementation of the BRC policy. The staff recognizes, in view of the invaluable potential information on human health effects arising from the accident at Chernobyl and the dramatic advances in molecular and cellular biology in the last 15 years, the need to maintain cognizance of the field and to reflect the new information in NRC's regulatory program. The importance of these events is described below.

The health effects from the Chernobyl release could be expected to provide information on the health effects of concern to the NRC, although only in the long term. The Soviets are willing to provide the opportunity to gather health effects data. However, they appear to have limited economic resources and thus plan only limited national support for this research. The US-USSR Joint Coordinating Committee for Civilian Nuclear Reactor Safety is currently preparing research protocols for work with the Soviets.

In regard to the need for evaluating the advances in biology, the staff is aware that a significant reduction in the uncertainties associated with risk coefficients might be achieved with a better understanding of the basic processes of radiation carcinogenesis and mutagenesis through studies on radiation effects at the molecular and cellular levels. Of course, the Departments of Energy and Health and Human Services have the major responsibility for health effects research. However, it is important that expertise in contemporary radiobiology be maintained within the staff to properly advise the Commission on and take advantage of advances in this science.

To this end, a research program is now underway assessing the utility of such studies to NRC programs and will be a catalyst for future cooperative research efforts in this area.

~~The infeasibility of conducting a~~ scientifically valid research program that could measure health effects, if any, due to BRC levels of radiation ~~precludes direct, periodic monitoring of the health effects resulting from implementation of the BRC policy.~~ However, the effectiveness of the BRC policy can be evaluated with a periodic review of the dose estimates from the aggregate of all the actual BRC practices that have been approved by the Commission. ~~The results of this periodic, aggregated evaluation coupled with continuous monitoring of the progress in radiobiology in the above examples, will provide scientifically valid and current information on the effects, if any, of the implementation of the BRC policy on health.~~ The frequency of the periodic evaluation of the aggregated doses ~~should depend on~~ the number and kinds of BRC practices that the Commission approves and that are implemented. If the number of approved BRC practices grows significantly, ~~the requirement for~~ additional resources ~~could be expected, either in the form of contractor or staff support, or both.~~

In regard to activity (7)(a), the evaluation of certain generally licensed devices for possible exemption under the policy statement, the analyses necessary are essentially the same as for the reevaluation of existing exemptions. Five devices were identified by the staff in SECY-90-175 as candidates for exemption: (i) static eliminators containing krypton-85; (ii) beta backscatter devices; (iii) gas chromatographs containing nickel-63; (iv) x-ray fluorescence analyzers containing cadmium-109 and iron-55, but excluding those containing curium-244 and americium-241; and (v) certain calibration and reference sources having small activities. Dose estimates will be made for comparison with the BRC criteria, and if necessary cost/benefit analyses will also be done. Because the work to be done on this task is the same as that for the reevaluation of existing exemptions and because of the importance of using a consistent approach, activities (3)(a) and (7)(a) will be carried out in combination with the assistance of a contractor.

Presuming that the above assessment indicates that certain generally licensed devices should be exempted under the BRC policy, appropriate rulemakings (activity (7)(b)) will be initiated in FY 1993 as shown in Enclosure 5. As many as five separate rulemakings may eventually be undertaken. Resource estimates for these rulemakings will be included in the next update of the Five-Year Plan if the evaluations demonstrate that exemptions are indeed appropriate.

Resources: The FY 1991-1995 Five-Year Plan includes resources to carry out all of the known activities described above. The FTE resources by Office for these activities are shown below:

	FY 91	FY 92	FY 93	FY 94	FY 95
RES FTE	7.0*	7.0	7.0	7.0	7.0
NMSS FTE	1.0	1.0	1.0	1.0	1.0
GPA FTE	1.9	1.6	1.4	0.3	0.3
ADM FTE	0.2	0.2	0.2	0.2	0.2
TOTAL	10.1	9.8	9.6	8.5	8.5

* Includes 2 overhire positions.

The above resource estimates generally represent minimum requirements which could be higher depending on the difficulty of the specific tasks identified. In addition to the NRC staff resources, an additional $0.5 million per year in contractor assistance has been included in the Five-Year Plan for the dose evaluations and the cost-benefit analyses of activities (3)(a) and (7)(a). However, the total cost of these activities cannot be determined at this time. The actual cost of the dose assessments will depend on the ~~availability of expertise and on the~~ extent that existing information can show consistency with the policy without extensive reevaluation. The total cost for the cost-benefit analyses and environmental assessments or impact statements will depend on the number of exemptions (and potential exemptions) with doses exceeding the criteria, on the complexities associated with the specific exemptions involved, and on the depth of the analysis necessary to determine consistency with the policy statement. Based upon previous experience, a full-~~scope~~ Environmental Impact Statement, if necessary for one of the more difficult exemptions, could cost $2 million. However, reexamination of some of the consumer products on a cost-benefit basis could be relatively simple in some cases and considerably less costly.

In addition, these estimates include resources for development of the rules described above but do not include resources for associated licensing and inspection activities. Resource

scope

requirements for these activities will be estimated in the regulatory analysis for each rule in accordance with standard procedure and cannot be foreseen in sufficient detail at this time to provide useful estimates.

As noted above, additional resources may also be needed: (1) as a result of the systematic assessment of existing exemptions, (2) if rulemakings are deemed appropriate for exempting certain generally licensed products, or (3) if a large number of documents such as regulatory guides, SRP's, branch positions are determined to need revision.

The FY 1991-1995 Five-Year Plan that was recently submitted to the Commission includes resources known to be needed to carry out the activities described in this plan. For 1991, one new FTE had been previously authorized for BRC, and RES is allowed two FTE's as overage positions. Starting in 1992, two FTE's per year will be reprogrammed from the high level waste program, a total of three additional FTE's per year. Some details of the assignments and specific tasks will have to be determined as the program proceeds and the results of the systematic assessment of existing exemptions and the evaluation of generally licensed devices become available. The staff will prepare a summary for Commission review when this effort is completed and the recommendations regarding rulemaking and regulatory guidance revisions are available.

Coordination: GPA has concurred in this staff plan. The Office of the General Counsel has no legal objection.

Recommendations: That the Commission note that:

1) The staff plans to proceed with the implementation of this plan unless otherwise directed by the Commission.

2) The resources necessary to implement known activities of this plan have been included in the FY 1991 - 1995 Five-Year Plan.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. SRM dated 10/13/89
2. SRM dated 6/28/90
3. SRM dated 8/13/90
4. List of Exemptions
5. Schedules
6. Guidance on Federal Register Notification dated 7/30/90

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