

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (EPA)
MODERNIZATION OF NIXON ERA RADIATION PROTECTION STANDARDS – AN
EXERCISE OF LEGAL RESPONSIBILITY TO PROTECT THE PUBLIC WITH SOUND
THEORETICAL AND TECHNICAL FOUNDATION OR ‘POLITICS AT PLAY’?**

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Abstract

In early February 2014, the United States Environmental Protection Agency (EPA) announced that “because of growing concern about greenhouse gas emissions from fossil fuels...a renewed interest in nuclear power” has occurred, and coupled with change in technology EPA felt that a “modernization” of radiation standards should take place. This perceived need for revised radiation standards stems from a projected growth of nuclear power, advances in radiation protection and dosimetry science, advances in radiation risk science, extended on-site storage of spent nuclear fuel, extension of nuclear reactor licenses, and ground water protection provisions. This paper compares the original EPA standards to the proposed revision of the radiation standard, and each standard’s set ability to meet the requirements in Title 40 of the Code of Federal Regulations (CFR) Part 190, whose two main obligations are: (1) a dose limit to members of the public, and (2) a radionuclide release limit to the environment. The EPA was delegated expressed authority in the Reorganization Plan No. 3 of 1970 (referred to as the parent act), to create standards/rules regarding radiation standard limits to judicate its obligation to protect the public and environment as outlined in the parent act. The 10th Circuit Court upheld that the Reorganization Plan § 2(a)(6) transferred to the EPA certain Atomic Energy Act (AEA) functions under AEA § 161(b) (*Quivira Mining v. U.S. Env’tl Prot. Agency*, 728 F.2d 477, 480 (10th Cir. 1984)).

This paper also investigates whether the radiation standards set(s) limits imposed (or to be imposed) meet the expressed delegated authority given in respect to the parent act or if the radiation standard set(s) act outside of the authority’s delegated powers and are thus *ultra vires*, ‘beyond the powers’. Further, following such a determination, the paper considers whether the proposed standards allows for the regulation of official discretion, by which in this context is meant “the extent to which officials...make decisions in the absence of previously fixed, relatively clear, and binding legal standards” (*Galligan* 1986:1), or if officials at the EPA are to apply the standards equally irrespective of the genuine difference in function. Therefore, a look at whether the standards revision is likely to stem from the need to take its first step from beliefs founded on less-than-certain theory and empirical evidence and/or related to any array of societal values and policy dispositions is examined. In addition, the question if the standards are

firmly rooted in technical foundations is discussed. In other words, are the aforementioned considerations a basis for legal nullification before the courts brought by dissenting parties is evaluated.

Finally, the 'protective' and 'facilitative' roles performed by the agency and the ability to balance politics' increasing role in shaping law, being influenced by societal values, and policy dispositions needs are evaluated. This brings forth the conclusion the dual roles cannot co-exist harmoniously under one roof and should be divided into two separate entities.

Introduction

Most people who live in the Southern states in the United States (US) are familiar with the expression "if it ain't broke, don't fix it", meaning that if it works adequately well leave it alone [1]. Humans, since the beginning of civilization seem to have an urge to constantly 'improve' things. For example, prehistoric hand-axes were made by repeatedly chipping small flakes off pebbles of flint with other hard objects. Example of these have been found that give the impression of being ruined by being chipped just one time too many. That pang of regret we have probably all felt after spoiling something by adding that unnecessary final touch is a constancy linking the generations [1]. An argument is made that regulatory bodies are often guilty of ruining the intent of the original act by means of creating regulations that are *ultra vires* 'beyond the powers' through the chipping away of the original legislation, from which it's authority precedes, just one time too many in the acting of regulating (of course, usually without that pang of regret).

On May 10, 1974, the United States (US) Environmental Protection Agency (EPA) published an advance notice of its intent to propose standards under its authority for the nuclear fuel cycle [15]. On May 29, 1975 the EPA released its proposed regulations in setting forth such standards [16]. The EPA enshrined the environmental radiation standards in the regulatory framework of the US in 1977 [17]. The standards specify the levels of public exposure and environmental releases below which normal operations of the uranium fuel cycle are determined to be environmentally acceptable [2]. In early 2014, the EPA published a notice requesting comments on its proposal to update its environmental radiation protection standards for nuclear power plants and fuel cycle facilities (40 CFR part 190). The EPA acknowledged that up to this time it had not sought, nor thought it necessary, to update these standards because little had changed in the industry, and that the "EPA believes the existing standards remain protective of public health and the environment" [3]. The EPA later said that the "[EPA] recognize[s] that they (40 CFR Part 190 issued in 1977) do not reflect the most recent scientific information" and therefore this is an "opportune time to conduct a thorough review of their continued applicability" [3]. In seeking comments and inputs, the EPA acknowledges that it does plan to revise its environmental radiation protection requirements to nuclear power operations (40 CFR Part 190) [4].

T. Bert (Thomas Bertram) Lance, the Director of the Office of Management and Budget in Jimmy Carter's 1977 administration (quoted in the newsletter of the US Chamber of Commerce, Nation's Business, May 1977) stated that "[he] believes [he] can save Uncle Sam billions if [he] can get the government to adopt a simple motto: "If it ain't broke, don't fix it." As Mr. Lance continues to explain "That's the trouble with government: Fixing things that aren't broken and not fixing things that are broken." It is worth noting that the intent of the EPA from the inception of setting the 1977 adopted standards is "to maintain a continuing review of the appropriateness of these environmental radiation standards and to formally review them at least every five years and to revise them if necessary" [2]. There is a role for the regulating agencies in setting 'broad' regulatory parameters, "but once those parameters have been established, regulation functions best at some remove from political influence of whatever hue" [5]. At question is, 'by having a politically appointed head, can the agency be insulated from political influence and not become a battlefield for quasi-political disputes'?

This paper looks into the delegated authority to the EPA providing a basis on which to act, the motivations which cause the EPA to review, revise and update the environmental radiation protection standards, seeks to determine if the proposed changes are the result of political belief/influence, or if the EPA is required to create standards based on advice and recommendation of professional/expert societies or may arbitrarily choose. Finally, the paper concludes that while there is a need “to maintain a continuing review of the appropriateness of [these] environmental radiation standards”, such activities must be done in a reasonable, and open approach that avoids any appearance of political motivation to ensure there is a sense of legal certainty and credibility in the regulations/standards established.

America’s Nuclear Foundation

America’s founding father of the nuclear regulatory framework is The Atomic Energy Act (AEA) of 1954 and this is the progenitor to all subsequent laws and the regulatory environment. The AEA declares, “Atomic energy is capable of application for peaceful as well as military purposes”. The government policy of the US with regards to atomic energy is to “develop[ment], use, and control atomic energy [shall proceed] with a direction to make “the maximum contribution to the general welfare” while attaching to this the paramount “objective to ensure security and common defense” [18]. The congress of the US submitted the following justifications for the regulation of the development, use and control of atomic energy (besides that of common defense and security) which are:

1. Processing and utilization of source, byproduct, and special nuclear material affect interstate and foreign commerce and therefore fall under the prerogative of congress under the Commerce Clause in the US Constitution¹.
2. Processing and utilization of source, byproduct, and nuclear material and source and special nuclear material, production facilities and utilization facilities must be regulated to provide for the protection of the health and safety of the public.
3. Funds of the US may be used to provide for the development and use of atomic energy with the aim to “provide for the common defense, promote the general welfare” of the American people and thus this regulatory authority is incumbent upon the federal government (congress) and not the states themselves to regulate. To promote the general welfare and the common defense the US may make funds available for a portion of damages suffered by the public from a nuclear incident and may be used to limit the liability of persons liable for the loss.

Federal courts have upheld the authority of congress in giving power to regulatory agencies (EPA) to establish environmental standards to protect the public from radiation exposure (see Nuclear Energy Institute, Inc. v. EPA, 373 F.3d 1251 (D.C. Cir. 2004). This section provides a brief historical overview of the development of nuclear energy, which led to the establishment of the environmental protection authorities. The EPA responsibilities in this area are also viewed (which were transferred to the EPA upon being established in 1970), as well as the review of the statutory authorities.

Historical Overview of Nuclear Power and the Creation of the Regulatory Framework

Since the dawn of the atomic age, the United States has been a leader in the development of nuclear fission to generate electricity. Nuclear fission has many benefits, and radioactive elements are useful to modern man in use of weapons and as a source of energy, as well as benefits in the medical field to provide information about the functioning of a person’s specific organs or to treat disease [6].

¹ The Commerce Clause refers to Article 1, Section 8, Clause 3 of the U.S. Constitution, which gives Congress the power “to regulate commerce with foreign nations, and among the several states, and with the Indian tribes.”

Sixty-nine years ago on August 06, 1945, the dawn of the nuclear age descended upon man when the atom bomb was dropped on the Japanese city of Hiroshima killing hundreds of thousands of people and destroying the surrounding environment almost instantly [7.]. Nuclear energy though is touted as a safe, stable, low cost, and reliable energy source that is also environmentally friendly [8]. Nuclear energy supplies nearly twenty percent of America's electricity [7]. Although nuclear power burns without emitting harmful greenhouse gases, it produces a potentially deadly and long-lasting byproduct: highly radioactive used nuclear fuel.

At massive levels, radiation exposure can cause sudden death.² Even at lower doses, radiation can have devastating health effects, including increased cancer risks and serious birth defects such as mental retardation, eye malformations, and small brain or head size³. Radioactive waste and its harmful consequences persist for time spans that are difficult to grasp. For example, iodine-129, one of the radionuclides expected to be buried at the proposed Yucca Mountain, has a half-life of seventeen million years⁴.

Due to the extremely harmful nature of the effects of radiation, there is a need to regulate the activities associated with the nuclear fuel cycle.

'New' Nuclear Regulatory Framework and Radiation Protection Authorities

The EPA was formed at the direction of President Nixon in 1970 due to concern that the "government's related activities have grown up piece-meal...[with a need] to organize them rationally and systemically" [9]. Section 161(b) of the Atomic Energy Act (AEA) authorized for the establishment of the Atomic Energy Commission (AEC) to "establish by rule, regulation, or order such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct as the Commission may deem necessary or desirable...to protect health and to minimize danger to life or property" [10]. In creating the EPA through the Reorganization Plan No. 3 (which became law on December 2, 1970), this consolidated the environment protection functions of several departments and agencies into the EPA. The EPA was generally provided research, monitoring, standard setting, and enforcement authorities for each category of pollutant. The transfer of radiation protection responsibilities was more limited, in that the authority to enforce radiation standards was retained by the AEC.

Reorganization Plan No. 3 of 1970 – The Transfer of Power to EPA

Prior to the formation of the EPA, radiation protection standard setting and guidance development authorities were housed in different organizations within the Executive Office of the President and various federal agencies in the executive branch [9]. Through the Reorganization Plan No. 3, a new national approach was adopted for protecting the general public from the harmful exposure to radiation. Two key radiation protection functions would be housed within the single agency [9], which are: (1) the promulgation of generally applicable environmental standards to limit man-made radioactive materials in the environment; and (2) the development of national radiation protection guidance for Federal and State agencies to follow in the development of their radiation protection programs and regulations [9].

² For further information and a more detailed description see National Institutes of Health, Fact Sheet: What We Know About Radiation, at <http://www.nih.gov/health/chip/od/radiation>

³ For further detailed information see Environmental Radiation Protection Standards for Yucca Mountain, Nevada, 64 Fed. Reg. 46,976, 46,978

⁴ For further detailed information see COMM. ON TECHNICAL BASES FOR YUCCA MOUNTAIN STANDARDS, NAT'L RESEARCH COUNCIL, TECHNICAL BASES FOR YUCCA MOUNTAIN STANDARDS 18-19 (1995)

By the enactment of the Reorganization Plan No. 3, President Nixon gave to the newly established agency “functions of the Atomic Energy Commission, administered through its Division of Radiation Protection Standards under the Atomic Energy Act of 1954, as amended...to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material.”⁵ The Reorganization Plan defined “standards” to mean “limits of radiation exposures or levels... of concentrations or quantities... of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material” [2]. Through this vehicle in how the term “standard” was defined for the purpose of the Reorganization Plan, this portion of the AEC’s authority under AEA section 161(b) that “consist[ed] in establishing general applicable environmental standards for the protection of the general environment from radioactive material⁶” was transferred to the EPA. Relying on this authority, in 1977, the EPA promulgated standards to protect the public from exposure to radiation from the uranium fuel cycle in 40 CFR part 190, “Environmental Radiation Protection Standards for Nuclear Power Operations”.

Nuclear Energy Institute, Inc. v. EPA (2004) - Courts Confirmation of EPA’s Statutory Authorities

The decision⁷ by the U.S. Court of Appeals for the District of Columbia concerning the Yucca Mountain repository (Yucca) involved challenges by the Nuclear Energy Institute (NEI), State of Nevada, and environmental groups. These groups had challenged the statutory and regulatory regimes of the EPA, Nuclear Regulatory Commission (NRC) and the Department of Energy (DOE) who each had various regulatory⁸ duties for the development of Yucca as provided for under the Nuclear Waste Policy Act (NWPA)⁹. The Court vacated the 10,000 year compliance period of the EPA rule as it found it to be inconsistent with section 801 (a) of the Energy Policy Act¹⁰. In addition, all challenges to actions of the secretary and president as well as challenges to the constitutionality of Congress’ Resolution under the NWPA in approving the Yucca Mountain site as the nation’s repository were considered.

There are two issues here that are valuable to focus on in regards to this paper’s discussion, which are: (1) The reaffirming and expansion of the court in the interpretation regarding the EPA’s authority (transferred from AEC) to establish environmental standards to protect the public from radiation exposure; and (2) the courts reaffirmation of the limit incumbent to regulatory agencies to work within the prevailing statutory scheme set by the congress. The court acknowledged if “the intent of the Congress is clear, that is the end of the matter¹¹” and that the courts¹² and the agency must give effect to the

⁵ See § 2(a)(6), 35 FR 15623. 15624 Reorganization Plan No. 3 (October 06. 1970)

⁶ Reorganization Plan § 2(a)(6); Also see *Quivira Mining v. U.S. Env’t Prot. Agency*, 728 F.2d 477, 480 (10th Cir. 1984) in which the court recognized that the Reorganization Plan transferred to the EPA certain AEA functions under AEA §161 (b)

⁷ *Nuclear Energy Institute Inc. v. Environmental Protection Agency*, 373 F.3d 1251, US Court of Appeals for the District of Columbia Circuit (2004).

⁸ 1) Regulations of the EPA “Public Health and Environmental Radiation Protection Standards for Yucca Mountain” at 40 C.F.R. Part 197; 2) NRC “Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada at 10 C.F.R. Part 63; and 3) DOE “Yucca Mountain Site Suitability Guidelines” at 10 C.F.R. Part 963.

⁹ NWPA, 42 U.S.C. 10101 et seq.

¹⁰ Energy Policy Act of 1992, Title XIII High-Level Radioactive Waste, Pub. L. No.102-486, 42 U.S.C. 10101 note

¹¹ *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)

¹² In judicial review procedues when a claim is presented before the court regarding the possiblity the agency has acted outside of its expressed authority (ultra vires – beyond the powers), the precedence of the courts has established a two part process (the Chevron Test) to determine if this is indeed the case (*Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) see also: *United States v. Mead Corp.*, 533 U.S. 218, 226-27, 121 S.Ct. 2164, 2170-71, 150 L.Ed.2d 292 (2001). The part of the Chevron test is to determine „whether congress has spoken to the precise question at issue“ being brought before the court. If the court finds that congress was clear on the issue, then the courts and agency must give way and let the voice of congress be heard. If the statue is „silent or ambiguous with respect to the specific issue“ the court will proceed to Chrevron’s second step, asking whether the agency’s interpretation is based on a permissible construction of the statute.” *Id.* at 843, 104 S.Ct. at 278. Though in this instance the court will defer to the agency statutory interpretations, “[our] the judicial function is neither rote nor meaningless,” *Natural Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 752 (D.C.Cir.2000), and the court will reject an interpretation “that diverges from any realistic meaning of the statute,” *id.* at 753 (quoting

unambiguously expressed intent.” In other words, the regulatory body’s desire to create regulation based on what it deems to be desirable has restrictions.

Reaffirming the Authorities of the EPA

The federal court in addressing the State of Nevada’s petition first made a determination in two areas of jurisdiction to hear the case, these being (1.) Subject Matter Jurisdiction¹³; and (2) EPA's claim that neither Nevada's nor the environmental petitioners' *constitutional standing*¹⁴ is "self-evident." For purposes of discussion, the jurisdiction of the court and its determination in the finding of jurisdiction is the most relevant.

In *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83 (1998) precedence was set in that the federal courts must ensure that they have jurisdiction before considering the merits of a case. In determining whether or not the court has jurisdiction in *Nuclear Energy Institute v. EPA*, the court used the jurisdictional statute found in the Hobbs Act. This gives courts of appeals exclusive jurisdiction to review orders issued by a host of federal agencies including the AEC, the Federal Communications Commission, and the Federal Maritime Commission. It should be noted, that in no place in the Hobbs Act is there a mention of the EPA. This then required the court to determine a direct lineage in the authorities of the EPA to those given by the congress to the AEC (See 28 U.S.C. § 2342 (2000)). Even though this is the case, the court felt that it “believes that the [Hobb’s] Act's conferral of jurisdiction over rules issued by the now-defunct AEC gives it [us] jurisdiction to entertain the petitions [in this case]”.

The Hobbs Act authorizes courts of appeals to review "all final orders of the Atomic Energy Commission made reviewable by section 2239 of title 42." Id. § 2342(4). In turn, section 2239 makes reviewable "[a]ny final order [of the Atomic Energy Commission]," (42 U.S.C. § 2239(b) (2000)), that is entered in "any proceeding for the issuance or modification of rules and regulations dealing with the activities of licensees," (id. § 2239(a)(1)(A)). As noted earlier, the AEC's authority to establish environmental standards to protect the public from radiation exposure provided for by congress in the AEA was transferred to the EPA upon the implementation of Reorganization Plan No. 3. The court, once again, reaffirmed this to be a fact in that the transferring to the EPA Administrator “functions of the Atomic Energy Commission...administered through its Division of Radiation Protection Standards, to the extent that such functions of the Commission consist of establishing generally applicable environmental

Massachusetts v. Dep't of Transp., 93 F.3d 890, 893 (D.C.Cir.1996)) (internal quotation marks omitted). [*Nuclear Energy Institute Inc. v. Environmental Protection Agency*, 373 F.3d 1251, US Court of Appeals for the District of Columbia Circuit (2004)]

¹³ See Halsbury’s Laws of England 1530. Judicial Review; in general. Judicial review is the process by which the High Court exercises its supervisory jurisdiction to review the lawfulness of an enactment or a decision, action or failure to act in relation to the exercise of a public function. “Challenging by way of a claim to review the lawfulness (judicial review) of decisions” (<https://www.lexisnexis.com/uk/legal/search/homesubmitForm.do>). Also see Halsbury’s Laws of England Volume 61 (2010) 5th addition: “601. General principles - The courts have an inherent jurisdiction to review the exercise by public bodies or officers of statutory powers impinging on legally recognised interests”. In addition, as regards specifically to the EU, judicial review is the fundamental means by which the actions of the applicable decision making bodies of the EU can be controlled. The EU has an original procedure that is unique – Preliminary Review Procedure: This allows for the private enforcement of EU Law. In the EU, private actions begin in national courts where private litigants assert their directly effective EU Law rights against the State or other private persons. This remedy which is specific to the EU system provides a view into the importance of the role of individuals being vital in the development of EU Law. See Craig and De Búrca, *EU Law* (Oxford, 2003), p. 472: “Article 267 TFEU gives the European Court the power to interpret the Treaty, but does not specifically empower it to apply the Treaty to the facts of a particular case. Indeed the very distinction between interpretation and application is meant to be one of the characteristic features of the division of authority between the ECJ and national courts: the former interprets the Treaty, the latter apply that interpretation to the facts of a particular case”.

¹⁴ “irreducible constitutional minimum” of standing, i.e., injury-in-fact, causation, and redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 2136-37, 119 L.Ed.2d 351 (1992). “The burden on a party challenging an administrative decision in the court of appeals is to show a substantial probability that it has been injured, that the [respondent] caused its injury, and that the court could redress that injury.” *Rainbow/PUSH Coalition v. FCC*, 330 F.3d 539, 542 (D.C.Cir.2003) (internal quotation marks omitted). Moreover, the asserted injury must be both “concrete and particularized” as well as “actual or imminent.” *Lujan*, 504 U.S. at 560, 112 S.Ct. at 2136.

standards for the protection of the general environment from radioactive material", is a reality and that the EPA is successor to them. As such, they are still 'living' and in force.

It has been firmly established in precedent that this transfer of authority was properly and fully undertaken. At least three circuits have held that "EPA action undertaken pursuant to EPA's AEC-transferred authority is reviewable under the Hobbs Act as if undertaken by the AEC itself"¹⁵. Going a step further to justify the basis for the claim of validity upon the transfer of authority, the U.S. Court of Appeals for the District of Columbia referred to its own precedence in which it has held "that agency action that "derives" from transferred authority is also reviewable under the Hobbs Act"¹⁶ (See *Aulenback, Inc. v. Fed. Highway Admin.*, 103 F.3d 156, 164-65 (D.C.Cir.1997)) (holding that the court had Hobbs Act jurisdiction to review Transportation Department rules addressing certain safety requirements because the agency's power to issue those requirements "derive[d] in part" from its transferred authority and because actions taken pursuant to that transferred authority were subject to Hobbs Act review).

The DC Court of Appeals left no doubt that the EPA has authorities to promulgate generally applicable standards to protect the public from radiation. In particular as regards to the EPA issuing its Yucca Mountain standards the court found the "EPA acted pursuant to authority derived from its AEC-transferred powers." Based on this case and previous precedence, it is clearly established that the EPA has the authorities to "establish[ing] generally applicable environmental standards for the protection of the general environment from radioactive material".

The EPA does have the authorities for creating radiation standards, and questions regarding whether this is to be the case, or not, have been firmly decided in established case law. It is no longer a question of 'in the use of its prerogatives to promulgate standards does the EPA act ultra vires, 'beyond the powers'?; the question becomes – 'do the standards themselves fit the concept of adequacy, or as Lord Drummond Young indicates, does the "desirability" for remedy of the identified insufficiency/deficiency "lead to provision over and above the standard of adequacy"¹⁷?

The interpretation of the word "desirable" is open-ended and as such may be used to stretch how the regulatory body dissects the language used in interpreting the statutory framework in place. Such a dissection in language provides the possibility for the regulatory body to regulate beyond the limits of adequacy or general intent by the congress or parliament. Therefore, one must ascertain the EPA's Creative Authority in creating radiation protection standards to determine if limitation has been placed in the statutory framework to provide a vantage point of view on the influence of acting in a political or scientific based manner in the regulation creation processes.

EPA's Creative Authority in Establishing Radiation Protection Standards

The maxim is *Qui tacet consentiret*: the maxim of the law is "Silence gives consent". "State regulation may be effected through the imposition of duties which are directly enforced by state agencies" in which these pursue the administrative policy which has been set for it in the 'parent' act from which is

¹⁵ See *Watkins*, 939 F.2d at 712 n. 4 (stating that EPA's generic health and safety standards for nuclear waste repositories are reviewable under 42 U.S.C. § 2239(b)); *NRDC v. EPA*, 824 F.2d at 1267 n. 7 (same); *Quivira Mining Co. v. United States EPA*, 728 F.2d 477, 481-84 (10th Cir.1984) (finding Hobbs Act jurisdiction over EPA regulations addressing radiation releases from uranium fuel cycle operations).

¹⁶ See *Aulenback, Inc. v. Fed. Highway Admin.*, 103 F.3d 156, 164-65 (D.C.Cir.1997) (holding that the court had Hobbs Act jurisdiction to review Transportation Department rules addressing certain safety requirements because the agency's power to issue those requirements "derive[d] in part" from its transferred authority and because actions taken pursuant to that transferred authority were subject to Hobbs Act review).

¹⁷ *R (on the application of *Assura Pharmacy Ltd*) v National Health Service Litigation Authority (Family Health Services Appeal Unit) and other applications [2008] EWHC 289 (Admin)

derives its authority and in which these often elaborates the details of the policy to “fill in the gaps”. To these non-judicial agencies are committed powers by the congress, which consist of the nature of legislating, judging, and executing. Administrative regulation is generally of a supplementary character, and this type of regulation is used to adapt broad and general terms found in bills passed by congress to the complex and widespread conditions which a law is trying to resolve. The power of an administrative agency to administer a congressionally created program necessarily requires the “formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress”¹⁸. The adaption is secured through the exercise of judicial discretion. The courts have held that an agency to which “Congress has delegated policymaking responsibilities may, within the limits of that delegation ... rely upon their own [the incumbent administration] views of wise policy to inform its judgments”¹⁹. If the Congress has maintained its silence on a principle and has explicitly left a gap for the agency to fill, then there is an express delegation of authority to act within the means available to reach a reasonable and necessary or desirable resolution. On this basis, it is interesting to note what the Congress implied or did not imply in the delegation of its legislative authority to the AEC to establish a regulatory framework within its statutory bounds.

Scope and Policy of AEC Regulation

Little guidance was actually provided by the Congress to the AEC regarding this completely unique and beneficial, yet destructive, powerful force in this new age that had dawned upon mankind; the “Atomic Age”. Nuclear physicist Alvin M. Weinberg had only some years before (1945) told the Senate’s Special Committee on Atomic Energy: “Atomic power can cure as well as kill. It can fertilize and enrich a region as well as devastate it. It can widen man’s horizons as well as force him back into the cave” [11].

The AEA was at its time of implementation the “broadest control ever exercised by the federal government over any one industry in the US” [12]. The overriding policy set by AEA for the AEC was to “encourage wide-spread participation in the development and utilization of the atomic energy for peaceful purposes.” At the same time as it anxiously engaged in the promotion of atomic energy, the AEC was to prepare regulations to protect public health from radiation. In creating regulations for dual purposes, which potentially could be in conflict with one another, which of the guiding principles was to be the overriding and take precedence?

The eagerness to push the rapid promotion of civilian nuclear development in 1954 stemmed from perceptions of the long-range need for new sources of energy, but the main driver was due to the need to provide an image that was seen to enhance America’s leadership in nuclear technology and its prestige [11]. Not only was such language evident in the construction of the AEA, the congress further expanded this intent behind the legislation in a study by the United States Joint Committee on Atomic Energy (1957). The committee studied three areas²⁰ of “perceived” problems that might require legislative action to remedy.

The third problem area of suggestion, which the committee investigated, was to make a determination whether or not the “Atomic Energy Act should be amended to separate the quasi-judicial from the development and promotional functions of the Commission” [13]. This notion that the first duty of the AEC is to promote atomic energy, was a top - down philosophy mandated by the congress to be the

¹⁸ Morton v. Ruiz, 415 U.S. 199, 231 (1974)

¹⁹ Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. 467 U.S. 837(No. 82-1005)

²⁰ (1) Make a determination whether or not the act “should require that public hearings be held before the grant or denial of a construction permit or license by the Commission.” (2) Make a determination in regards to requiring “that all reports on reactor safety be made public as soon as completed.”

heartbeat in the rhythm of the commission for drafting the necessary and desired regulatory language. Indeed, the AEC understood this to be so, and “attached great significance to the need [during the period ahead] for a singleness of administration of the Government’s activities in atomic energy, be they regulatory, promotional or direct operational in nature” [13]. The idea that politics could be a fundamental reason for consideration during the preparation of regulation for the use of atomic energy in the regulatory and licensing space has been evident since the inception of the AEC and continues from that time period through to today in these functions which were transferred to the EPA.

EPA and Administrative Law Making

Generally, congress enacts a new regulatory program or will expand an existing program due to a need that has become apparent to protect the public or environment from some type of abuse by a person or corporate entity. It is suggested that the protective purposes of regulatory programs “are often undermined through a slow process of erosion, drift or slippage, [and] as beneficiary groups engage in what Professor Eugene Bardach calls “the implementation game”” during the policy making process [14].

Under the conventional model of administration rulemaking, an agency should initiate the endeavor by assembling and analyzing all the relevant technical studies to understand all the various aspects in how the proposed regulation will affect the citizenry. In drafting a notice of the proposed rulemaking, the preamble will highlight the issues to discuss, followed by the scientific, technical, and economic studies it intends to undertake, with a conclusion to explain the proposal. The agency is then required to present the draft proposal to the Office of Information and Regulatory Affairs (OIRA) in the office of Management and Budget (OMB). OIRA then sends the proposal to various departments and agencies that have an interest in the regulation or any changes to the regulation for comments on the regulatory impact analysis. Once the draft proposal has cleared this OIRA review, the agency will then publish a notice in the Federal Register for public comment, which is open for a set period. The agency will analyze the comments and will draft a notice for final rulemaking in which it sets the terms and conditions of the final rule. What is most important in this process is that the agency explains the rationale for how it made the determination in the creation of the rule and how it responded to the public comments, which have crossed a threshold of competent understanding. Affected parties may then seek a judicial review of the agency’s new rule²¹, in which regulated industry may often challenge the action in court that the rule is arbitrary and capricious, ultra vires, or both. If the challenge against the agency prevails in court, the agency must either terminate the action or attempt to correct the infirmity, which the court has identified. Congress has tried to bring some conformity to the rule-making process to try and limit the amount of “politics” in the rule-making process through the passage of the Administrative Procedure Act (APA)²². Congress, presidents and the courts have added to the procedural protections of Section 553²³ of the APA requirements that agencies must provide support for scientific and technical conclusions in a “rulemaking record”, must respond to public comments that pass a threshold of competent understanding, and prepare an analysis of the impact of the regulation, which mostly take consideration of economic impacts [14].

The ‘Necessary’ and ‘Desirable’

²¹ See Mcgarity, TO 2012, 'ADMINISTRATIVE LAW AS BLOOD SPORT: POLICY EROSION IN A HIGHLY PARTISAN AGE', Duke Law Journal, 61, 8, pp. 1671-1762; for a more detailed view outlining the rulemaking process see Anne Joseph O’Connell, Agency Rulemaking and Political Transition, 105 NW. U.L. REV.471, 476 (2011) .

²² Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, 701-706 (2006)

²³ See APA §4, 5 U.S.C. 553 (listing the basic procedural requirements for agency rulemaking)

In section 161 (b) of the AEA the AEC was given power by the congress to “establish by rule, regulation, or order such standards and instructions...as the Commission may deem necessary or desirable to promote the common defense and security or protect health and to minimize danger to life.” Note here that the AEC was allowed flexibility to create standards that it feels are “necessary” and/or “desirable” and the congress did not spell out precisely what the body is to do, but gave indication of the over-all purpose/intent.

The standard of the court is that unless specific statutory requirements exist regarding certain basic rules of procedure, then the agency’s reasoning for the construct of the written regulation is the superior authority on that particular subject matter. American Administrative law comprises the means through which regulations are written by the interpretative nature of the regulatory body to craft regulation based on legislation. This process is added upon by the role of a court when it conducts judicial review of the regulations in comparison to the original legislation. This allowance of function of the American regulatory bodies is in sharp contrast to that of the British regulatory bodies. American regulatory bodies made be deemed as a “State within a State”, while naming the British ones as “‘semi-autonomous’ bodies” is usually a stretch. A look at the construction in how each system’s courts parcels the definition of the word “desirable” is valuable to note, as this gives expression for latitude by an Administrative body to further powers in creating regulations. Therefore, to ascertain a construction to the possible definitions in law of the term “desirable” is certainly relevant.

As stated in the US legal system, the standard for Administrative law making is that the agency states the reasons and the justification for its “desire²⁴” to regulate and the court follows the agency’s lead. In the British system, the court acts in much more of the advisory role seeking to provide guidance to the directed agency, almost like a wise older father leading a child. For instance, in *R (on the application of Assura Pharmacy Ltd) v National Health Service Litigation Authority (Family Health Services Appeal Unit) and other applications* [2008] EWHC 289 (Admin) the court offered guidance to those involved in making and deciding applications to be admitted to the National Health Service Pharmaceutical List of a particular primary care trust under reg. 12 of the National Health Service (Pharmaceutical Services) Regulations 2005. Parliament was clear in its direction that admissions of applications “shall be granted only if necessary or desirable to secure services in a neighborhood” (‘the necessary or desirable test’). It was then up to the regulatory body to consider whether the necessary or desirable test is satisfied in making a judgment of allowance to each particular request submitted. This is that the decision-maker must make a determination if the provisions in place are adequate for the purpose (per the various specifications listed in the regulation). The weight attached to these factors relating to the provisions in place and any other relevant factor is thus a burden of reality on the shoulders of the decision-maker. Where the provision in question easily satisfies the identified standard of adequacy, the decision maker should so state giving his reasoning.

In this sphere of decision making (where terminology is comparable to that of the spectrum of color when a ray of light has been refracted through a prism) one must view the term ‘wholly adequate’ as terminology that conveys the necessary image (as does ‘wholly inadequate’), in that these terms relate to where the situation/provision easily ‘satisfied’ or easily ‘failed to satisfy’ the standard in question. However, as the court found in this particular instance, the standard set by Parliament is not “that the provision has to be of a standard greater than adequate.” A finding by the decision-maker that the provision is adequate or inadequate is the only requirement, and such a finding is necessary and sufficient to the necessary image, as did ‘wholly inadequate’ where the provision easily failed to satisfy that standard. As Parliament granted powers to the regulatory body to act as the appropriate decision-maker,

²⁴ In other words why the regulation is desirable, i.e., “Wanted or wished for as being an attractive, useful, or necessary course of action” http://www.oxforddictionaries.com/us/definition/american_english/desirable

and as the exercise requires the exercise of a qualitative value judgment, the discretion then is deemed by both the parliament and the court to be a wide one. If the decision-maker finds the provision to be adequate to the purpose in question then no further action needs to happen. If the decision-maker finds the provision to be inadequate, then he has to consider how that deficiency could be remedied, i.e. to consider whether the proposal is 'necessary or desirable'. Lord Drummond Young states that the Court of Sessions has construed "adequacy" as an absolute concept, but has noted that "desirability" has been interpreted by the courts as means of allowing for the regulatory body to make decisions in which this would not only remedy the identified insufficiency/deficiency, but "lead to provision over and above the standard of adequacy".

This allowance by the courts in the interpretation of the word "desirable", to stretch the interpretation of the statutory framework in place, provides the possibility for the regulatory body to regulate somewhat beyond the limits of adequacy, as stated by the congress or parliament. This opens the door to regulatory bodies to create regulations under its authority that are more political based than scientific ones, especially where congress or parliament has been silent or ambiguous on the issue. Though both administrative systems vary in nature, the courts in each have allowed latitude and flexibility of the administrative body's qualitative discretion in providing a value judgment when so required following a 'desire' to regulate.

The above constitute the only limitations to the creative authority in the rule making processes of the EPA in the creation of generally applicable radiation protection standards. As such, it may be viewed that the EPA has unlimited license to create standards it deems necessary and desirable.

Conclusion

The EPA has wide latitude in its creative authority in the rulemaking process, which is only subject to the limits of the rulemaking processes described in the APA, as well as any limitations, which may be found in the parent act from which it derives its authority, (which in this instance is open to what the EPA believe is 'necessary' and 'desirable'). In the AEA, the only requirement of the EPA is to ensure safety in the creation of radiation protection standards. Therefore, only time will tell if the process to change the Nixon era radiation protection standards is based on science, politics, or a combination of both as the efforts to update the standards moves forward. There are no direct statements by the congress which limits the rulemaking effort of the EPA. As long as the EPA can provide a reasonable justification for how it arrived at its conclusions, then the courts will generally not overrule the decisions of the EPA.

That being said however, given the clear understanding of the wide consequences in the use of atomic energy in that it can "widen man's horizons as well as force him back into the cave" [11], there is an ever incumbent duty on the congress and the EPA to ensure that trust and integrity in the regulatory process is maintained to provide a sense of confidence in the regulatory [legal] certainty by the citizenry. This is that the overriding desire of the EPA to protect the public from the effects of radiation, and the desire of the congress to assist in the promotion of the use of atomic energy function together in a harmonious and open manner in an agency with a politically appointed head where regulations are debated in an overheated political environment.

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