Low-Level Waste Regulation: Putting Principles Into Practice - 13297

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ABSTRACT

In carrying out its mission to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment, the U.S. Nuclear Regulatory Commission (NRC) adheres to its Principles of Good Regulation. The Principles—Independence, Openness, Efficiency, Clarity, and Reliability—apply to the agency as a whole in its decisionmaking and to the individual conduct of NRC employees. This paper describes the application of the Principles in a real-life staff activity, a guidance document used in the NRC's low-level radioactive waste (LLW) program, the Concentration Averaging and Encapsulation Branch Technical Position (CA BTP). The staff's process to revise the document, as well as the final content of the document, were influenced by following the Principles. For example, consistent with the Openness Principle, the staff conducted a number of outreach activities and received many comments on three drafts of the document. Stakeholder comments affected the final staff positions in some cases. The revised CA BTP, once implemented, is expected to improve management and disposal of LLW in the United States. Its positions have an improved nexus to health and safety; are more performance-based than previously, thus providing licensees with options for how they achieve the required outcome of protecting an inadvertent human intruder into a disposal facility; and provide for disposal of more sealed radioactive sources, which are a potential threat to national security.

INTRODUCTION

Although less frequently discussed than its risk-informed, performance-based regulatory policy,[2] NRC's Principles of Good Regulation also guide the work of the agency and the staff in carrying

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[2] Risk-informed regulation is a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. Performance-based regulation is a regulatory approach that focuses on desired, measurable outcomes, rather than prescriptive processes,

out its mission to ensure safety in the beneficial uses of radioactive materials.[3] The Principles—Independence, Openness, Efficiency, Clarity, and Reliability—are to be applied to the agency as a whole in its decisionmaking and to the individual conduct of NRC employees. They are described as fundamental guideposts in ensuring "the quality, correctness and consistency of our regulatory activities." The Principles also articulate the standards by which the regulated community and broader public can judge the NRC as a regulator [1].

The purpose of this paper is to discuss the application of these Principles in a practical, real-life NRC staff activity, the revision of the CA BTP. The Principles are just that—principles, or high-level guides. There is flexibility in how they can be interpreted and implemented. In addition, some exist in tension with each other and need to be in balance. For these reasons it is instructive to examine how the Principles have been implemented in practice and how they have influenced the actions of the staff and the content of the final regulatory guidance.

NRC's PRINCIPLES OF GOOD REGULATION

The Principles are intended as guide to both agency decisionmaking and the individual conduct of NRC employees, and are the standards by which the regulated community and broader public is asked to judge the NRC as a regulator and as an institution charged with achieving and maintaining the public trust [1]. Initiated by former Commissioner Kenneth Rogers and published by the Commission in 1991, most of the basic ideas in the Principles of Good Regulation were not completely new to the NRC. Qualities such as independence and openness had long been considered objectives of Agency performance, according to a Commission staff member involved in their development [2]. In relating the history of the development of the Principles, it is noted that the explanatory statements were intended to focus attention on the most important performance measures and to help assure that everyone understood all the goals in the same way.

The five Principles of Good Regulation are:

Independence: Nothing but the highest possible standards of ethical performance and professionalism should influence regulation. However, independence does not imply isolation. All available facts and opinions must be sought openly from licensees and other interested members of the public. The many and possibly conflicting public interests involved must be considered. Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated.

Openness: Nuclear regulation is the public's business, and it must be transacted publicly and candidly. The public must be informed about and have the opportunity to participate in the regulatory processes as required by law. Open channels of communication must be maintained with Congress,

techniques, or procedures. Performance-based regulation leads to defined results without specific direction regarding how those results are to be obtained.

[3] For example, a Yahoo web search of the terms "NRC" and "Principles of Good Regulation" had 61 hits. A web search of the terms "NRC" and "risk-informed, performance-based" had 2100 hits.

other government agencies, licensees, and the public, as well as with the international nuclear community.

Efficiency: The American taxpayer, the rate-paying consumer, and licensees are all entitled to the best possible management and administration of regulatory activities. The highest technical and managerial competence is required, and must be a constant agency goal. NRC must establish means to evaluate and continually upgrade its regulatory capabilities. Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay.

Clarity: Regulations should be coherent, logical, and practical. There should be a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Agency positions should be readily understood and easily applied.

Reliability: Regulations should be based on the best available knowledge from research and operational experience. Systems interactions, technological uncertainties, and the diversity of licensees and regulatory activities must all be taken into account so that risks are maintained at an acceptably low level. Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.

In their more than 20 years of existence, the Principles have become part of the culture, i.e., the core values and behavior of NRC. Many are implemented in processes and procedures, without necessarily being explicitly identified. For Openness, as an example, NRC has procedures for communicating with stakeholders, including development of a communications plan and identification of stakeholders and outreach techniques to improve Openness and stakeholder engagement. It is now commonplace for the staff to hold public meetings or facilitated workshops associated with the development of rules and guidance, even though a notice and comment period would be legally sufficient. At the same time, several NRC Commissioners have recently highlighted the Principles for their continuing relevance to the agency's work and external stakeholders occasionally refer to the Principles in their expectations for the agency[3] [4] [5] .

This paper examines a specific staff activity, the revision to the CA BTP, to illustrate how the staff has implemented the Principles in a practical, real-life activity, and the effects of implementing the Principles on the staff's work.

CONCENTRATION AVERAGING AND ENCAPSULATION BRANCH TECHNICAL POSITION

Background

The CA BTP addresses a single sentence in NRC's regulations—"concentrations of waste may be averaged for the purposes of determining their waste class." This sentence is embedded in NRC's LLW disposal regulation in 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." Part 61 defines the requirements for licensing a LLW disposal facility. The concentration averaging provision acknowledges that such averaging is permitted, but provides no details on how this provision should be implemented. The purpose of the CA BTP is to provide guidance that explains to licensees, Agreement State regulators, and others how the averaging requirement in the regulations can be met. The guidance helps to ensure that "hot spots" in LLW are constrained, both in their size and their radioactivity concentration, to ensure protection of public health and safety.

The connection between averaging waste concentrations and protection of public health and safety begins with one of the four performance objectives in 10 CFR Part 61. One of them, 10 CFR 61.42, requires the protection of any individual who inadvertently intrudes into a licensed disposal site and occupies the site or contacts the waste at any time after active institutional controls over the disposal site are removed. One measures to protect an inadvertent intruder in 10 CFR Part 61is to classify waste according to its hazard and apply more stringent measures to isolate the waste with increasing hazard and waste class. For example, Class A waste, the lowest hazard class, is generally safe after 100 years, while Class C, the highest hazard waste, has controls that must last for 500 years before the hazard is reduced to acceptable levels through radioactive decay. Waste classes are defined in tables in 10 CFR 61.55, which lists specific radionuclides and their concentrations for each class. For example, Cs-137 has a Class A limit of 1 Ci/m^3 and a Class C limit of 4600 Ci/m^3. I-129 has a Class A limit of 0.008 Ci/m^3 and Class C limit of 0.08 Ci/m^3.

The concentration limits in the 10 CFR Part 61 waste classification system in 10 CFR 61.55 were developed for *average* concentrations of wastes. The staff did not consider hot spots in the development of the waste classification requirements, other than to specify in 10 CFR Part 61 that averaging of wastes (i.e., hot spots) was acceptable, but without defining the conditions and constraints on such averaging. The regulation does not answer the questions, "How much waste above the limits is permissible, how much more concentrated than the limit can this waste be, and over what volume are these concentrations to be measured?" The CA BTP does. Because non-radioactive material is also sometimes added to LLW (e.g., cement solidification of liquid waste), the CA BTP also answers the question, "How much non-radioactive material can be mixed with LLW?" This answer limits extreme measures of adding non-radioactive material to waste, diluting the concentrations of radionuclides to circumvent stricter disposal requirements. The averaging constraints in the CA BTP help to ensure that an inadvertent intruder into a disposal site, upon contacting "hot spots" from such activities as excavating trenches for a public works project or drilling a well, will not receive an unsafe exposure to radioactivity.

Despite its narrow focus, this guidance is widely used—by thousands of LLW generators; by the waste processing industry; by the four operating LLW disposal sites; and by the Agreement States that regulate many generators of LLW and almost all of the LLW processors in the U.S. It is also of interest to the LLW Compacts that are responsible for regulating the import and export of LLW from within their borders, as well as advocacy groups concerned with issues related to the health and safety of LLW facilities. The CA BTP is used for the classification of the thousands of shipments of waste that are made each year to disposal facilities, and its guidance can help licensees determine exactly how waste can be managed and disposed of at particular facility. The CA BTP guidance helps to ensure that the risk from disposal of LLW is managed appropriately and that the public is protected from the effects of its radioactivity, both now and in the distant future.

The CA BTP has evolved over the 30 years since it was first published. NRC's concentration averaging guidance was originally contained in a single page in the May 11, 1983, Branch Technical Position, "Final Waste Classification and Waste Form Technical Position Papers" [6]. On January 17, 1995, NRC staff replaced that guidance with the "Branch Technical Position on Concentration Averaging and Encapsulation"[7]. The 1995 CA BTP was a significant expansion of the agency's guidance, from one page in 1983 to 21 pages. The purpose of the expansion was to achieve greater consistency in averaging approaches among the NRC and Agreement State regulators [8]. In the 18 years since this revision was published, there have been internal and external developments that caused the staff to initiate revisions to the CA BTP.

Drivers for Revising the 1995 CA BTP

In 2007, the NRC staff performed a strategic assessment of the NRC's regulatory program for LLW to identify its highest priority work, primarily based on the status of the national LLW program. For the CA BTP, a number of factors led to its classification as a high priority to update. They included:

- The document was written before NRC's adoption of its risk-informed, performance-based regulatory policy. Many of its positions did not have a direct connection to human health and safety. In fact, a number of the CA BTP positions were designed to achieve *uniformity* in the waste concentrations (i.e., not much variability around an average concentration), but often without a clear connection to protection of public health and safety. For example, the CA BTP recommended that for a mixture of solid, discrete radioactive items in a container, such as activated hardware from the core of a nuclear power reactor, the radioactivity concentrations of items in the mixture be within a certain concentration of each other, even if radioactivity in the hottest piece in the mixture is well below the waste classification limit. In addition, the 1995 CA BTP was not fully performance based. It discouraged licensees from using alternatives that could achieve the desired outcome—to minimize hot spots so that an inadvertent intruder would not receive an unsafe exposure to radioactivity.

- The only operating disposal facility that accepted Class B/C wastes from most generators in the U.S. was to close for many of them in mid-2008. With that closure, generators had no disposal option for these wastes. The staff realized that revisions to the CA BTP had

the potential to increase the flexibility of disposal of certain types of LLW, particularly sealed sources and irradiated hardware, without compromising safety. The strategic assessment stated that the staff would use risk-informed approaches and knowledge that were not available when the CA BTP was developed and last updated in 1995.

- In 2008, an industry proposal for large-scale blending of ion exchange resins was put forth. The concept involved the mixing of Class B and C concentrations with Class A concentrations of resins to form a Class A final mixture that would be suitable for disposal at another facility available to most generators. Such processing was to be performed offsite at a waste processor, and would significantly change the management of resins that had been in practice. Up to that time, resins were either disposed of directly from nuclear power plants, or processed without extensive mixing of higher and lower concentrations. The CA BTP did not specifically address this situation, and the proposal was controversial among stakeholders.

- After 9/11, the United States identified sealed radioactive sources as posing a potential national security threat if used in a dirty bomb, and sealed source disposal, the safest and most secure method for managing sources, was significantly and sometimes unnecessarily constrained by the CA BTP.

The next section describes revisions to the 1995 CA BTP to address the above challenges and changes in the LLW program.

Improvements in the Revised CA BTP

After identifying the revision of the CA BTP as a high priority task, the staff initiated a process to accomplish that task. Three drafts were issued for public comment and the final CA BTP is expected to be issued later this year. The following are the major improvements to the CA BTP.

Blending of waste—for mixing of blendable or flowable wastes, such as ion exchange resins, the CA BTP now has a risk-informed, performance-based position. Previously, the 1995 CA BTP recommended constraints on the *inputs* to a mixture rather than the *output* of the mixing processes. The characteristics of the final mixture, or output—i.e., its average concentration and degree of homogeneity—potentially affect the protection of an inadvertent human intruder, not the concentrations of waste prior to mixing. The 1995 CA BTP recommended that inputs be no more than a factor of 10 different from the average concentration of the final mixture. The revised CA BTP does not constrain inputs but specifies a homogeneity test for the final mixture in certain cases, based on radiation exposures to an inadvertent intruder.

Mixtures of solid items—for mixtures of discrete solid items, such as activated metals from a nuclear power plant, the CA BTP recommends constraints on how concentrated the radioactivity can be in individual items, since these items can vary considerably in their radioactivity concentration. Discrete, solid radioactive items that remain intact for long periods of time after disposal, such as those made of stainless steel, pose a hazard to an intruder who would handle the item without recognizing the hazard and receive a radiation exposure. In the 1995 CA BTP,

individual pieces were recommended to have radionuclide concentrations no more than a factor of 1.5 or 10 different from the average of the mixture. The factor of 1.5 applied to radionuclides that emit gamma radiation, which are more hazardous for discrete items, and the factor of 10 to the other two types of radioactive emissions, alpha and beta radiation. As with blended waste, this guidance is not risk-informed. A *uniform* mixture, the outcome of following the 1995 guidance, has no direct connection to the risk to the intruder. While it is possible that for mixtures that are near the concentration limits for a particular waste class, the uniformity imposed by the factor of 1.5 and 10 will ensure intruder protection, many other mixtures will be below and even well below the limits for waste classes. Thus, the guidance ensures uniformity, but with no strong connection to the acceptable radiation dose associated with the waste class limit. The revised CA BTP recommends constraints that are tied to radiation exposure to an inadvertent intruder. Specifically, gamma emitting radionuclides in an individual item are recommended to be within a factor of 2 of the waste class concentration limits and a factor of 10 for non-gammas.

Encapsulation of sealed sources—encapsulation is the use of non-radioactive material to surround a source of LLW within a container. Both the 1995 and the revised CA BTP constrain the amount of credit that can be taken for non-radioactive material in determining the waste class and average concentration. Using non-radioactive materials to artificially lower the concentration of LLW would enable some high hazard radioactive wastes to be disposed of in as a lesser waste class with fewer controls, and thus increase the risk to an inadvertent intruder. The revised CA BTP specifies constraints for encapsulation that are based on more reasonable, but still conservative exposure scenarios for an inadvertent intruder. For example, for Cs-137, one of the common radionuclides used in sealed sources for cancer treatment, the recommended Class C constraint has been increased from 30 Ci to 130 Ci, based on new analysis. Because sealed sources, especially Cs-137 sources, have the potential to be used in radiological dispersal devices, or dirty bombs, making disposal available for these sources, rather than storage where the sources could more easily be stolen, enhances national security.

Performance-based regulatory policy—the 1995 CA BTP established a high bar for deviating from the recommendations in the position. It states that alternative approaches for averaging should be approved under NRC's regulation in 10 CFR 61.58, "Alternative *requirements* [emphasis added] for waste classification and waste characteristics." This provision states that "The Commission, upon request, may authorize provisions for the classification and characteristics of waste on a specific basis if, after evaluation of the specific characteristics of the waste, disposal site, and method of disposal, it finds reasonable assurance of compliance with the performance objectives in Subpart C of 10 CFR Part 61." By referencing a provision in the regulations that applies to alternatives to the requirements in 10 CFR Part 61 (and not NRC staff guidance like the CA BTP), the staff in effect discouraged performance-based approaches to intruder protection. Only one different averaging approach was approved by regulators in the eighteen years since the CA BTP was published. The staff believes that this provision of the 1995 CA BTP has deterred licensees from proposing different averaging approaches. In addition, not all regulatory authorities for States that license disposal sites have this provision in their regulations, and so the regulatory mechanism for obtaining approval of alternatives is not even available to all licensees.

The newly revised CA BTP, instead of referring to 10 CFR 61.58 for obtaining approval of alternative approaches to averaging, uses language consistent with other NRC guidance documents. It states that the guidance is provided to describe, and make available to NRC licensees, Agreement States, and the public, methods that the NRC staff believes may be acceptable for implementing specific parts of the Commission's regulations, and to provide advice to regulated entities. It notes that its positions are not intended as substitutes for regulations, and compliance with them is not required. The revised CA BTP also identifies considerations and criteria to be considered for alternative approaches that could be approved by regulators in a license condition, for example.

Averaging Constraints for Cartridge Filters—cartridge filters are a significant waste stream for nuclear power reactors. Typically containing filter media in a perforated metal housing, these filters remove solid radioactive particulates in water used in various reactor systems. The 1995 CA BTP classified filters as discrete solid items subject to the factors of 1.5 and 10 averaging constraints. As such, each filter must be characterized and then packaged in a container so that these averaging constraints are met. Based on information received from stakeholders concerning the hazard associated with these filters, the revised CA BTP enables licensees to justify treatment of the filters as homogeneous waste not subject to averaging constraints. Licensees must document the basis for the deviation, which could be that the hazard to an intruder is not significant based on the radionuclide concentrations and/or physical configuration of the filters.

These revisions to the CA BTP, when implemented, are expected to have significant benefits in improving the management of LLW in the United States. The revised positions are much better tied to NRC's risk-informed, performance-based regulatory policy, and will continue to ensure protection of an inadvertent intruder into a disposal site. Some ancillary benefits are that unnecessary worker exposures from sampling and measurements have been eliminated or reduced, and sealed sources which pose a potential threat to national security will have more disposal options.

While these results are beneficial in and of themselves, the purpose of this paper is to ask the question, "How did NRC's Principles of Good Regulation affect the process for revising the CA BTP and the final staff positions in the document?" The next section answers this question.

APPLICATION OF THE PRINCIPLES OF GOOD REGULATION

The CA BTP is particularly well-suited as an example of the application of the Principles. First, this document affects a variety of stakeholders with significantly different views about how the concentrations of radioactive waste should be averaged. They include an estimated several thousand LLW generators and the industry groups that represent them; Agreement States that regulate all four of the LLW disposal sites in the United States and most of the waste processing facilities; advocacy groups that follow LLW disposal nationally and locally; waste processors; LLW Compacts that have authority under the Low-Level Radioactive Waste Policy Amendments Act of 1985 to develop disposal capacity for their generators and to regulate the import and export of waste from their compacts; and disposal facility operators. Thus, NRC's

Openness Principle was particularly important in this revision both in encouraging outreach to the many stakeholders and in understanding their disparate views. A second important consideration for the revisions to this document is that the LLW program has been long established and has an excellent record of safe disposal. Some disposal facilities have been licensed and in operation for more than 40 years. NRC's disposal regulations were promulgated more than 30 years ago and continue to be the primary regulatory standard for the operating disposal facilities. The 1995 CA BTP has been in place for 18 years. Thus, there is a well-established framework that generators, processors, disposal facility operators and their regulators have been using, which has ensured safe disposal and has been largely accepted by stakeholders. NRC's Reliability Principle values the existing regulations, stating that regulations should not be unjustifiably in a state of transition, and that regulatory actions should lend stability to the nuclear operational and planning process.

At the same time, the 1995 CA BTP was issued before the agency's adoption of its risk-informed, performance-based regulatory policy. A number of its positions are not directly tied to protection of public health and safety. Several positions are not performance-based, and instead prescribe specific, detailed criteria that licensees are constrained to follow, as described earlier. These constraints have a significant impact on the management of LLW in the United States, including unnecessarily constraining the disposal of sealed sources.

Finally, the 1995 CA BTP was written for a narrow set of practitioners in the nuclear waste management field. Many stakeholders believed that it needed to be written for a larger audience and to be more transparent in the bases for its positions. Clarity, or the Principle that regulations should have a clear nexus to regulations and agency goals and objectives, was an area of improvement for the CA BTP, in the view of the NRC staff and stakeholders in general.

NRC strives to fulfill all of the Principles in its work, but certain aspects of each are worthy of highlighting because of their relevance to this task. Listed below are the five Principles along with several key points about each.

Independence and Openness

The first Principle, Independence, states, among other things, that it does not imply isolation and that "all available facts and opinions must be sought openly from licensees and other interested members of the public. The many and possibly conflicting public interests involved must be considered. Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated." Independence is related to the Openness Principle, which entreaties the staff to provide opportunities for the public to participate in the regulatory process and to inform the staff of its views.

Since the Principles of Good Regulation were first developed, NRC staff has expanded its public outreach efforts so that more than a Federal Register notice are routinely used to obtain stakeholder views. In the case of the CA BTP, the first public outreach focused on LLW blending. In 2008, licensees and industry were considering the blending of certain types of LLW to help mitigate the impact of the closure of the only LLW disposal facility for disposal of Class B/C wastes from most U.S. licensees. One type of waste being considered for blending was ion

exchange resins from nuclear power plants, which can be blended into a relatively uniform mixture. These resins account for about half of the volume of Class B and C waste generated each year. Resins were the focus of a waste processor's expanded LLW blending at its facility in the State of Tennessee.

Many stakeholders had a significant interest in this topic, ranging from waste management companies whose business models were potentially affected by the proposal, to States that regulate the facilities processing or disposing of blending waste, to advocacy groups, and to LLW generators who would potentially benefit from blending. Given this interest, the Commission and staff took a number of steps to obtain information from all stakeholders for this issue, which included:

- Site visits to the waste processing facilities that treat ion-exchange resins, including the proposed facility for large-scale blending
- Public meetings with three companies potentially affected by large-scale blending
- A facilitated public workshop with stakeholders representing disposal companies, waste processors, generators, States, and others
- A public comment period that was noticed in the Federal Register
- A Commission meeting in which the Commission received testimony directly from the NRC staff, and representatives from advocacy groups, generators, waste processors, disposal facility operators, and Agreement States regulators on a staff paper on LLW blending. That paper, SECY-10-0043, "Blending of Low-Level Radioactive Waste," analyzed the issues raised by stakeholders [9]

The Commission issued its decision on LLW blending in October 2010, enabling the staff to begin work on incorporating the decision into CA BTP and revising other areas of the document.

Other sections of the CA BTP address averaging of mixtures of individual solid items of waste. These items include cartridge filters and activated metals from nuclear power plants and sealed sources. The CA BTP recommends constraints on individual items that are averaged over the waste volume, to limit the size and radioactivity concentration of "hot spots" in LLW, thus protecting a potential inadvertent intruder into a disposal facility. As with the blending issue, the staff engaged stakeholders in developing revised averaging positions in the CA BTP. These interactions included:

- A facilitated public workshop at NRC Headquarters. Stakeholders included representatives from the Conference of Radiation Control Program Directors, disposal facility operators, the Agreement States, advocacy groups, and LLW generators
- Public comment periods for three drafts of the CA BTP
- A public meeting in Albuquerque, NM to receive stakeholder comments
- Staff presentations on the CA BTP in four LLW Forum meetings
- Staff presentations and responses to questions in two meetings with the LLW Forum's Disused Source Working Group

- Staff presentations at two of the Electric Power Research Institute's annual LLW Conferences
- Staff presentations at the annual Radwaste Summit
- Staff presentations at the annual Waste Management Conferences

After public comment periods or workshops, the staff analyzed issues raised and considered whether revisions to the CA BTP positions were appropriate. Stakeholder comments in some cases caused the staff to revise positions in the CA BTP:

- The staff's test for homogeneity of mixable waste in the August 2011 draft was based on a conservative analysis of the radiation exposure to an inadvertent intruder to hot spots in waste not thoroughly mixed. Stakeholders argued that the new test would require significantly more surveys to demonstrate compliance. The staff agreed that the proposed test could be difficult to implement and was contrary to "as low as is reasonably achievable" (ALARA) principles. In the final CA BTP, the staff took several steps to minimize the measurements made to demonstrate waste homogeneity, including establishment of a threshold for testing; specifying a larger volume of waste, which is expected to require fewer measurements; development of alternate approaches based on site- or waste-specific information to reduce or eliminate the need for testing; and encouragement for the use of process knowledge and reasoned conclusions instead of direct measurements.

- Although the staff had proposed an "Alternative Approaches" section of the first draft revision of the CA BTP that would enable licensees to propose other averaging methods, some stakeholders, including the ACRS, recommended that criteria be identified for each that would enable licensees and Agreement State regulators to more efficiently address key variables affecting the adequacy of an Alternative Approach. The final CA BTP contains detailed criteria for each example approach, and stakeholders in general support the additional guidance on alternative approaches. The revised CA BTP will be more efficient for licensees and regulators.

- With respect to sealed source disposal, the U.S. Department of Energy National Nuclear Security Administration made a number of specific suggestions for the CA BTP revision that would enable safe disposal of Class B/C sources that were not allowed under the existing CA BTP. These included allowance for shielding and greater averaging volumes, as well as specific considerations for site-specific determinations. Most of the DOE suggested changes were adopted in the final CA BTP.

- As a result of stakeholder comments and data, the staff revised its position for averaging of cartridge filters, one of the major nuclear power reactor waste streams. Because cartridge filters often may not present a discrete, "hot spot" hazard with significant gamma radiation, the staff inserted a provision into the CA BTP that

> enables licensees to provide a written justification for averaging cartridge filters without constraints, provided certain criteria are met.

While the above interactions make it clear that the staff did not act in isolation and was pro-active in seeking stakeholder views, the Independence Principle also states that "[F]inal decisions are to be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated." To this end, the staff prepared more than 150 pages of responses to stakeholder comments in revising the CA BTP. Final staff positions were based on protecting an inadvertent intruder into a disposal site, to fulfill NRC's public health and safety mission. Detailed technical and safety analyses in the CA BTP support the staff's positions on safety. In addition, legal requirements, precedents established for particular issues in either NRC or other waste management programs, or some combination of these were also factors in decisionmaking. When stakeholders submitted data to support their position, the staff independently verified the data using other sources.

A number of stakeholder suggestions were also not adopted in the final CA BTP. For LLW blending, for example, the stakeholder views ranged from not allowing waste blending that would reduce Class B/C concentrations to Class A waste to eliminating the homogeneity test entirely for blended LLW. The former was contrary to the Commission decision on LLW blending, and for the latter, the staff believes a homogeneity demonstration of some blended waste is needed to ensure intruder protection, one of the requirements in NRC's disposal regulation in 10 CFR Part 61. Other stakeholder suggestions were not consistent with NRC's regulations, such as allowing for reliance on greater than 100 years for institutional controls, or did not provide adequate protection of an inadvertent intruder.

Clarity

The Clarity Principle also influenced the revisions to the CA BTP. The 1995 CA BTP was written for a small audience of LLW practitioners and was therefore difficult for other stakeholders that did not routinely work with it to fully understand the positions or their bases. In revising the CA BTP, the staff reconsidered the audience for whom the CA BTP should be "… readily understood and easily applied," as stated in the Clarity Principle. A challenge for clarity is that the averaging positions are inherently complex. They are based on hypothetical scenarios of human intrusion into a disposal facility and the accompanying dose modeling that involves assumptions about time of exposure to radioactivity, the distance the intruder is from the radiation source, the severity of hot spots, and other factors. In general, simple positions could be formulated that could provide reasonable assurance of safety of an inadvertent intruder, but these simple positions would be overly conservative in many cases. In these cases, increased complexity enables generators and disposal facility operators to manage their waste in more efficient ways. Simpler, more readily understandable positions may preclude more detailed approaches that offer benefits such as reduced worker exposures.

Notwithstanding the above, the staff has endeavored to revise the CA BTP for a broader audience of LLW program professionals. These include not just the day-to-day users, but also new staff working in LLW, as well as a broader cross section of regulators, processors, disposal

facility operators, and other interested groups. The CA BTP has more background material, more documentation of the technical bases for its positions, and significantly more analysis of stakeholder comments (more than 150 pages versus 12 in the 1995 CA BTP) which further elaborates on the bases for many of the positions. Because many users of the CA BTP would not be interested in the extensive analysis of comments, these have been included in a separate volume. The staff has also included general information on the revised CA BTP on NRC's public web site, and is preparing an implementation plan that will, at the request of stakeholders, address training of users after it is completed.

Reliability

The Reliability Principle states that "Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition." The CA BTP is a regulatory guidance document, but is like a regulation in some cases because it is incorporated into several disposal facility licenses. Some stakeholders argued for sweeping changes to the CA BTP, including the elimination of many of the averaging constraints. Others argued for maintaining stability and minimizing changes, an interest of some States that have relied on the CA BTP for regulating their disposal facilities. Maintaining public trust and acceptance is important to them. As NRC guidance that is not subject to NRC's compatibility requirements for regulations, the CA BTP does not have to be adopted by States.

The staff believes that maintaining the "frame" of the 1995 CA BTP provides regulatory stability. That frame includes specification of generic averaging constraints, consistent with the use of a generic waste classification system in 10 CFR Part 61. It also includes the 1995 CA BTP's position that hot spots pose a unique hazard that was not analyzed in the development of 10 CFR Part 61. One stakeholder recommendation was that the CA BTP, which is based on generic averaging positions that can be used by any LLW disposal facility in the United States, be replaced with a site-specific approach. The staff continues to specify generic averaging approaches, which are more risk-informed and performance-based than the 1995 CA BTP, because they are easier to use than site-specific approaches and they provide for safe disposal. At the same time, the revised CA BTP has significantly expanded criteria for site-specific approaches, should licensees wish to choose that approach.

Efficiency

In writing about the development of the Principles, one of the lead Commission staff recently wrote about the Efficiency Principle, "Here, I note the delicate balance we had to achieve. We wanted to convey the sense that the action should be as fast as possible, but it should not be done carelessly. Data needs to be gathered and assessed, and if you are serious about seeking the views of stakeholders, that takes time [10]." In revising the CA BTP, this writer believes that the many stakeholder outreach efforts—public meetings, facilitated workshops, a Commission meeting, documenting responses to comments, and the publication of three drafts for comment—have been necessary and valuable, and that the process could not be rushed. For example, NRC took one year to address LLW blending, beginning with direction to write a paper for the Commission until the Commission decision was issued. In that year, the staff conducted a public workshop; researched and analyzed issues related to blending, including many raised by stakeholders; completed a lengthy Commission paper; and testified before the Commission. The

Commission decision has since been widely accepted by stakeholders. In another example, during an October 2011 workshop to receive public comments on a draft of the CA BTP, stakeholders requested that the staff extend the schedule for publishing a subsequent draft for comment. At the time, the staff had not planned to revise the CA BTP based on workshop comments before publishing it for formal written comments. Stakeholders requested that the staff, however, consider all of the comments from the workshop first. This approach enabled stakeholders to provide comments on a draft that reflected the staff's thinking on all comments that had been received up to that time.

SUMMARY

NRC's Principles of Good Regulation—Independence, Openness, Efficiency, Clarity, and Reliability—apply to the agency as a whole in its decisionmaking and to the individual conduct of NRC employees. In their more than 20 years of existence, the Principles have become part of the culture, i.e., the core values and behavior of NRC. Many are implemented in processes and procedures, without necessarily being explicitly identified.

This paper has described the application of the Principles in specific and real-life staff activity, a major guidance document used in the NRC's LLW program. Using the Principles as a guide, the staff's process to revise the document, as well as the final content of the document, were affected. Consistent with the Openness Principle, and because of the significant stakeholder interest in the document, the staff conducted a number of outreach activities and received many comments on early drafts of the document. All comments were analyzed and responses to each were documented. Not all of the stakeholder comments affected the content of the final CA BTP, but a number did, particularly those that provided information relating to practical consequences of staff positions, such as increases in worker exposures as a result of staff positions. Independence, Clarity and Reliability were also important. The Commission's direction to be independent but not isolated was implemented in connection with seeking stakeholder views. Clarity was important in establishing who the intended audience was for the document, and in documenting at length the basis for the revised positions and the resolution of stakeholder comments. Reliability was also important in being mindful of changes to the existing guidance and practices for concentration averaging and for intruder protection, which have been in place for decades. The staff was also mindful of Efficiency throughout the process, but found that the stakeholder outreach, while useful to staff and to stakeholders, has a significant impact on schedule.

The revised CA BTP, once implemented, is expected to improve management and disposal of LLW in the United States. Its positions have an improved nexus to health and safety; are more performance-based, thus providing licensees with options that can achieve the desired outcome of protecting an inadvertent intruder; and provide for disposal of more sealed radioactive sources, which are a potential threat to national security.

The Principles are described as fundamental guideposts in ensuring "the quality, correctness and consistency of our regulatory activities." The Principles also articulate the standards by which the regulated community and broader public can judge the NRC as a regulator. This paper is

intended to inform the regulated community and other interested members of the public how the Principles have been used as guideposts in revising a specific staff guidance document.

REFERENCES

1. Svinicki, C., U.S. Nuclear Regulatory Commission,"State of the Nuclear Renaissance—A Regulatory Perspective." Capital Hill Symposium VIII sponsored by the U.S. Nuclear Infrastructure Council. June 8, 2010. ADAMS Accession No. ML101590318

2. Marcus, G., "Principles of Good Regulation: A Little History," Nuke Power Talk, March 13, 2010. http://nukepowertalk.blogspot.com/2010/03/principles-of-good-regulation.html

3. Ostendorff, W.C., U.S. Nuclear Regulatory Commission, "Initial Impressions of a New Commissioner," Remarks at the NRC 2011 Regulatory Information Conference, March 8, 2011.

4. Svinicki, March 9, 2010, U.S. Nuclear Regulatory Commission, Remarks at the NRC 2010 Regulatory Information Conference. http://video.nrc.gov/MediaPlayer.php?view_id=2&clip_id=84

5. Magette, T., EnergySolutions, letter to Annette Vietti-Cook, U.S. Nuclear Regulatory Commission, July 31, 2012. ADAMS Accession No. ML12216A228.

6. NRC, 1983, "Final Waste Classification and Waste Form Technical Position Papers," dated May 11, 1983, Federal Register, (4 8FR 26295). ADAMS Accession No. ML033630755.

7. NRC, 1995, "Branch Technical Position on Concentration Averaging and Encapsulation," January 17, 1995. ADAMS Accession No. ML033630732.

8. NRC, 1995, "Availability of Final Staff Technical Position on Concentration Averaging and Encapsulation," Federal Register, (60 FR 4451).

9. NRC, 2010, "Blending of Low-Level Radioactive Waste," SECY-10-0043. ADAMS Accession No. ML090410246.

10. Marcus, G., Japan NUS Co., Dr. Marcus' Room, "NRC's Principles of Good Regulation," November 2010. http://www.janus.co.jp/essays/marcus/goodregulation-e.html