NRC Requests Input on ^{131}I Information Resources

The U.S. Nuclear Regulatory Commission (NRC) announced on November 16 in the *Federal Register* (2015;80[220]:70843–70856) a broad request for information from the general public and the medical community on several issues associated with ^{131}I treatment. The NRC requested: (1) input on patient concerns about medical treatment involving the use of ^{131}I; (2) details on information that physicians use to make decisions on when it is safe to release ^{131}I-treated patients based on radiation exposure concerns; (3) radiation safety information given to and used by these patients after their release; and (4) and radiation safety information guidance, either already existing or as preparation for an NRC brochure for ^{131}I patients. Information collected in this effort will be used to develop a website to provide patients with "clear and consistent information about radioactive iodine treatments" and to "revise NRC patient release guidance." The agency identified a February 16 deadline for submission of information and comments.

Background

In a March 10, 2014, memorandum, NRC Chair Allison MacFarlane, PhD, and Commissioner William Magwood, IV, questioned whether patients receiving ^{131}I treatments are given consistent and useful information from medical facilities and whether release instructions can be easily understood and followed. Anecdotal data from patients and patient advocacy groups indicated that although instructions are provided, the quality of these instructions varies and that some patients are provided with instructions that both patients and medical facilities know is impractical and will be difficult to follow. The NRC subsequently directed its staff to develop a website to provide patients with clear and concise information and links to relevant medical and patient advocacy websites about ^{131}I treatment, to revise NRC guidance to specify guidelines for patient instructions and information (including a voluntary model patient/licensee acknowledgement form documenting the dialog leading to the licensee's decision of when to safely release the patient based on radiation exposure concerns), and to develop a standard set of guidelines that licensees can use to provide instructions to released ^{131}I patients. Staff was also directed to consider whether the information provided to patients can be made into an NRC brochure or whether a professional organization already has (or would produce) such a brochure for distribution.

Information Requested

NRC indicated in its *Federal Register* announcement an interest in obtaining input in the form of comments and information from as many stakeholders as possible, including the NRC's Advisory Committee on the Medical Use of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested entities. Following are excerpts from the request for information, including the level of detail the NRC is targeting.

Web Site Information. NRC is considering "establishing a Web site that provides potential patients with information on RAI [radioactive iodine] treatment procedures so that patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others. Some of this is medical information that is outside the NRC's field of expertise. The NRC would like to be able to provide links to other sites providing this medical information. The NRC may develop the basic radiation safety information itself, but could provide links if established sites already have this information." NRC is also seeking "input from patients, patient advocacy groups, and other interested individuals to articulate concerns that may not be included in the topics identified in this section. If you have, or know of, a Web site that that can be used to explain the disease and treatment process, and addresses one or more of the following topics, please provide the link to the NRC: What is radioactivity? What is RAI? Any explanation of how radiation is used in the treatment should include clear information that the patient will receive radioactive material, emit radiation, retain radioactive material, and release radioactive material. What to expect before and after receiving the treatment. Side effects of RAI treatment. Basic radiation safety: Appropriate venues for recovery after release. Precautions to take after receiving treatment. Risks to others, to include risks to young children and pregnant women. Expected general behaviors after release."

Patient/Licensee Acknowledgment Form and Best Practices About Patient Release. NRC is looking for "best practices used by individual physicians and licensees that focus on enhancing the ability to make informed radiation safety decisions on the release of individual patients from their radiation safety control under the patient release criteria in the NRC's medical use regulations. The NRC expects the physician (licensee) to have a dialog with the patient that will ultimately lead to an informed decision on when the patient should be released from its radiation safety control based on radiation exposure considerations (this includes immediate or delayed release, in addition to hospitalization)." The NRC is also interested in knowing "whether a patient/licensee acknowledgment form documenting this dialog exists and is part of the physicians' best practices. The NRC believes this dialog would include some or all of the following: The patient's ability to understand the language of the physician (licensee) or need for an interpreter that understands the procedure. The need for a family member or another support person present to facilitate better retention of information. A discussion with the patient to determine suitability for release. Description of the patient's transportation from the medical facility to home. Discussion of the patient's normal daily behavior and patterns, including but not limited to: The patient's normal/routine social interactions. The patient's

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using external scintillation counting (a prototype of the Mark IV scanner). Sokoloff, along with Reivich and Kuhl, reached out to Alfred Wolf, PhD, from the Brookhaven National Laboratory (Upton, NY) for assistance with identifying and synthesizing a longer-lived isotope for brain imaging. Wolf's team synthesized ^{18}F-FDG, as reported by a combined Penn, Brookhaven, University of California at Los Angeles (UCLA), and NIH team in 1979. Michael Phelps, PhD, and Edward Hoffman, PhD, at UCLA, adapted ^{18}F-FDG for use with their PET technology. Throughout this period of intense and pioneering investigation into functional imaging, Sokoloff served as a bridge among researchers at different institutions and with varying approaches to instrumentation development.

Sokoloff, who retired from the Laboratory for Cerebral Metabolism in 1999 and remained at NIH as an emeritus scientist, was a past president of the American Society for Neurochemistry and the Association for Research in Nervous and Mental Disease. With his NIH colleagues and coinvestigators from across the United States he published hundreds of peer-reviewed articles. In 1981 Sokoloff received the Albert Lasker Clinical Medical Research Award from the Albert and Mary Lasker Foundation, which emphasized the importance of his brain mapping techniques in driving new and innovative methods for assessing brain function. In acknowledging his achievements, the award committee cited Sokoloff for "developing a pioneering method which enables scientists to visualize the simultaneous biochemical activity of an entire network of neural pathways in the brain and central nervous system. This new method maps and measures their functioning, both as a whole and in localized areas, under both normal and abnormal conditions," adding that "Dr. Sokoloff's brilliant contributions constitute a prime example of a bridge that leads from basic laboratory research to clinical application that can benefit literally millions of people everywhere." Sokoloff also contributed detailed and insightful obituaries of his noted colleagues, including Kety and Kaufman, to the scientific literature.

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normal/routine working environment and tasks. The patient's normal/routine living arrangements. The planned changes to the patient's normal/routine behaviors during the treatment period (have friend or family member accompany the patient or spend time with patient, change in living arrangements, etc.). Financial considerations that will affect the patient's preference on early or delayed release. Discussion to evaluate patient's ability to understand and follow instructions. Discussion to evaluate patient's willingness to follow instructions. Discussion to evaluate the level of disruption to patient routine lifestyle, if released, and the ability of the patient to make and follow the changes, if released." NRC is calling for providers to offer descriptions of policies and procedures as well as for patient input on optimal timing for discussions about release.

Guidance for Released Patients. NRC staff has been directed to develop "standardized guidance for licensees to provide to their patients that would help to reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding the type of information that is provided to the patient." The request for information noted that "While the NRC currently prefers to develop performance-based guidance (articulating objectives but not telling licensees how to reach those objectives), prescriptive guidance (i.e., very detailed and specific) may be necessary to reduce uncertainty and provide confidence that regulatory requirements are met. If the standardized guidance is performance-based, it would need to provide individual patients with the 'tools' needed to follow the objectives in the guidance and protect others." NRC is calling for copies of guidance documents currently in use that effectively address these and other topics/issues: What ''tools'' (or methods/means) can the patient use to protect others once released? Are both oral and written information presented in the patient's native language and presented in a manner understandable to both the patient and physician (licensee)? Does the medical facility/licensee have access to an interpreting service to make sure that oral and written information and instructions are understood? How are instructions personalized to the individual patient? Does the medical facility explain how to limit the exposures to others (especially to young children and pregnant women)?

Brochure for Nationwide Use. The NRC is also seeking to identify an existing brochure that offers clear guidance on the release of patients treated with ^{131}I.

Responses and comments can be submitted at http://www.regulations.gov (search for Docket ID NRC–2015–0020) or by mail to Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.