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Dr. Robert G. Claypool, Deputy Chief Medical Officer
Office of Public Health and Emergency Preparedness
Department of Health and Human Services,
200 Independence Avenue, SW
Room 638 G
Washington, DC 20201
By Email: Robert.Claypool@hhs.gov

Dear Dr. Claypool:

On behalf of Nuclear Information and Resource Service (NIRS), I am filing comments regarding the United States Health and Human Services draft Federal Guidelines for Requesting Potassium Iodide (KI) from the Strategic National Stockpile as provided under Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

NIRS finds the HHS draft document deficient in its content, meaningful procedures and guidelines. As such, the document is inadequate as written in a number of vital areas necessary to develop publicly acceptable guidelines for a federal KI distribution strategy.

1) The HHS draft document on a KI distribution strategy lacks content on the attributes of incorporating the prophylactic drug into a national emergency response strategy for radiological events.

The HHS document does not provide any measure of background for the extensive support of the medical community, such as the American Thyroid Association, for the development and implementation of an effective distribution program for the prophylactic use of KI in the event of radiological emergency. The HHS document does not provide the acknowledgement that KI is a safe and provenly effective prophylactic drug for preventing the uptake of radioactive iodine to the thyroid, particularly for children. The HHS document does not provide any reference to the proven effectiveness of KI in preventing childhood thyroid abnormalities and aggressive cancers to populations in Poland that continue to afflict eastern and central European populations exposed to radioactive iodine in the fallout from the 1986 Chornobyl nuclear accident.

2) The KI distribution strategy for a 20-mile radius is inadequate and invites chaos in the aftermath of a nuclear accident or act of radiological sabotage.

NIRS argues that to limit the expansion of the KI stockpile and distribution area from the 10-mile radius Emergency Planning Zone to a mere 20-mile radius is to severely underplan for a significant radiological emergency and invite chaos into the aftermath of an accident or act of sabotage affecting large sectors of the population who will be justifiably be seeking the prophylactic use of KI. NIRS argues that to limit the KI distribution strategy to a 20-mile radius ignores the far reaching consequences of a radiological accident as has already been amply demonstrated to the world by the 1986 Chernobyl nuclear accident.

NIRS urges the HHS to expand the distribution area for KI out to the 50-mile radius, at minimum, to encompass the currently designated Ingestion Pathway Zone as acknowledged in NUREG-0654/FEMA-REP-1 Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for every nuclear power station in the United States.

It has been widely reported through responsible and respected journalism to the American public that Poland was prepared to promptly distribute stockpiles of KI to its nation's children in the aftermath of the 1986 Chernobyl nuclear accident in Ukraine over 180 miles from the Polish-Ukrainian border.

As CNN reported:

“Nuclear bombs or emergencies, such as the Chernobyl nuclear reactor accident of 1986 in Ukraine, are potential sources of radioiodine exposure. Immediately after the Chernobyl accident, a radioactive cloud spread over many parts of Europe. As many as 3,000 people in Ukraine, Belarus and Russia who were exposed to radiation from that accident have since developed thyroid cancer. Most cases of radiation-induced thyroid cancer take between eight and 20 years to develop. Because of this, a 2002 United Nations report suggests that cases of thyroid cancer related to the Chernobyl disaster could more than triple in the next 10 years.

Meanwhile, cases of thyroid cancer have not increased in Poland, which borders Ukraine to the west. Poland's prompt and efficient distribution of KI pills may have prevented many potential cases of radiation-induced thyroid cancer. “¹

Therefore, it is documented and identified to the American people that the consequences radioactive iodine released from the Chernobyl nuclear accident extended far beyond the HHS limited proposed 20-mile radius. Why has HHS ignored this fact and historical event in its draft statement?

The American Thyroid Association (ATA) has similarly acknowledged and advocated for the need to have in place a distribution strategy of KI to an area larger than the HHS proposed 20-mile radius as was discussed at the ATA 2002-2003 Symposium on KI:

¹ <http://www.cnn.com/HEALTH/library/CC/00027.html>, “Potassium iodide pills: Protection against radiation exposure,” November 18, 2003.

“The seminal event that opened the world’s eyes to the importance of KI distribution was the Chernobyl nuclear accident, releasing a fallout cloud that spread radioactive iodine and other radionuclides throughout eastern and central Europe. Starting a few years later, infants and children who had been exposed to the fallout were diagnosed with an unusual and aggressive form of thyroid cancer, except in Poland where the government had distributed KI pills... The center of much debate at the symposium was the length of time it has taken for the U.S. government to recognize that KI needs to be made available for communities at highest risk. After decades of inaction on this issue, in December 2001, the Nuclear Regulatory Commission offered free KI pills to the 34 states that either have nuclear reactors or are within 10 miles of another state’s plant. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 calls for distribution of KI to people living within 20 miles of nuclear facilities, as of June 2003. The ATA supports this action but advocates much wider KI distribution.”²

NIRS is puzzled how the eyes of HHS have not been opened to the far reaching consequences of radioactive iodine releases and how such consequences are relatively easy to mitigate with an effective KI distribution policy and distribution strategy as demonstrated by the Chernobyl accident and the Polish government’s prepared response.

In fact, the American public expects effective KI prophylactic protection through the educational efforts of its own media and such experts as members of the American Thyroid Association. Such effective educational efforts have focused protective KI actions that go beyond the HHS limited 20-mile radius.

In event of a radiological accident or act of sabotage, the American public, particularly those living within the 50-mile radius of the Emergency Plan for nuclear power stations will be seeking KI prophylactic protection. If such a prophylactic response is not available to those populations in a timely fashion the HHS limited focus has invited a chaotic response.

As defined by federal emergency plans and regulations, the Ingestion Pathway Zone is the minimum area that the federal government is responsible for the providing protective actions to populations to prevent or minimize internal radiation exposures.

In fact, HHS acknowledges in its Purpose statement of the draft:

“The timely use of KI is an accepted intervention to block the thyroid gland from incorporating radioactive iodine that individuals have either ingested or inhaled.”

HHS draft statement then goes on to contradict itself by misinterpreting the intent of protective actions to be taken within the Ingestion Pathway Emergency Planning Zone when it states, “the primary concern in this zone is from ingestion, not inhalation, of radioactive materials from the plume.” If populations are receiving internal radiation

² http://www.thyroid.org/professionals/publications/documents/News_summary.pdf

“Experts Discuss Potassium Iodide Distribution in Case of Nuclear Incident,” American Thyroid Association, 2002-2003.

exposure from an inhalation dose as opposed to an ingested dose what worth is a protective action strategy, particularly for such vulnerable populations as children?

NIRS argues that the intent of such protective actions is to minimize internal radiation exposures to populations within the 50-mile radius, and in the case of radioactive iodine, KI provides effective protection if taken in a timely basis. A well thought out and all encompassing distribution strategy is critical to providing critical population sectors (i.e. children) with protective actions in a timely manner following a radiological incident.

HHS can not justifiably defend any conclusion suggesting that a significant radioactive iodine release does not represent a sickening and potentially fatal internal exposure to downwind populations at a minimum of 50-miles from a radiological event site. Therefore, HHS attempts to limit its KI distribution strategy to a 20-mile radius is as unreasonable, arbitrary and capricious as the nuclear industry effort to originally limit the distribution of KI only to station personnel and emergency workers.

3) HHS has ignored instructions from Congress

NIRS submits that HHS has ignored instructions from Congress to develop meaningful and effective guidelines for “distribution and utilization of potassium iodide tablets in the event of a nuclear incident.”

HHS was instructed to produce “Federal Guidelines for Requesting Potassium Iodide (KI) from the Strategic National Stockpile,” as indicated in the title of the document sent out for comment, however, the agency has failed to provide any evidence that it has given any thought on such guidelines.

For example, HHS draft guidelines state that KI is available as an over-the-counter medication for persons wishing to acquire it in instances where it is not provided by a government program. Such pandering ignores specific Congressional instructions to develop guidelines for distribution and utilization. Drugstore managers are not required to order or maintain stocks of KI. Drugstore managers that do stock KI do not factor in critical and updated census figures for local, seasonal, vacation and recreational populations and other considerations to assure adequate stocks would be available in the event of a nuclear accident or act of sabotage.

In so far as HHS has ignored its instructions, the agency has taken on the same glacial pace that has plagued the Nuclear Regulatory Commission since the March 28, 1979 Three Mile Island nuclear power station accident which prompted the re-evaluation of the failure of emergency planning and implementation in U.S. policy on potassium iodide prophylaxis. NRC’s stonewalling and policy paralysis ultimately led Congress to removing NRC altogether from formulation of Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In fact, Congress provided that the National Academy of Sciences (NAS) would conduct the study of potassium iodide (“to determine the most effective and safe way to distribute and administer potassium iodide on a mass scale,” Section 127(e)(2)(A)). NIRS is puzzled by HHS absence of communication with NAS who authored the KI study in an effort to formulate

any meaningful guidelines. Perhaps it would have resulted in something other than the current complete absence of guidelines.

4) HHS ignored soliciting comment from the potentially impacted public around nuclear power stations.

NIRS submits that HHS ignored taking any meaningful comments from potentially impacted communities in the development of a KI distribution and strategy by failing to put out a draft policy statement for broader public comment in the Federal Register. Instead, HHS relied on comments from the Governors of States, who have had a historically long and conflicted history of influence by the nuclear industry agenda which has opposed KI distribution from the beginning.

NIRS notes the Federal Emergency Management Agency (FEMA) noticed the public in a "Notice of Revised Policy" on its federal policy on use of potassium iodide in Federal Register, January 10, 2002, Volume 67, Number 7.

NIRS further notes that Food and Drug Administration (FDA) in Federal Register (March 8, 2004 (Volume 69, Number 45)) solicited public comment by announcing the availability of a guidance for Federal agencies and State and local governments entitled "Potassium Iodide Tablets Shelf Life Extension." The document was intended to provide guidance to Federal agencies and to State and local governments on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets.

Similarly, FDA provided the public with earlier notice on extending the shelf life of KI in Federal Register, April 2, 2003, Volume 68, Number 63.

It is conspicuous that HHS made no effort to solicit public comment on the development of an effective and meaningful distribution strategy for potassium iodide from potentially impacted communities. The HHS failure to solicit professional and public comment through the Federal Register grossly undermines the development of effective and accepted policy on this important public health and safety strategy.

If revised federal policy adopting KI as a prophylactic strategy for the public and evaluating shelf life extension on potassium iodide all warranted posting in the Federal Register, why was public notification and comment completely ignored on the vitally important distribution strategy?

Conclusion

Therefore, NIRS submits that the HHS draft should be withdrawn and that the agency should rewrite a draft in accordance with the requirements of the Bioterrorism Act, Section 127, and then broadly circulated to all stakeholders and placed in the Federal Register for extensive public comment

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