be deemed to be “interoperable” if that software has been certified by a certifying body recognized by the Secretary within 12 months prior to the donation. Under the interim guidance for the recognition of certifying bodies published by the ONC (“Office of the National Coordinator for Health Information Technology (ONC) Interim Guidance Regarding the Recognition of Certification Bodies”), for an organization to be recognized as a certified body (RCB), the organization must:

- Have in place a demonstrated process by which they certify products to be in compliance with criteria recognized by the Secretary;
- Have a method by which they can incorporate all applicable standards and certification criteria into their certification processes; and
- Have the ability to adapt their processes to emerging certification criteria recognized by the Secretary.

The RCBs would therefore have to certify such products in conformity with, among other provisions, these interoperability specifications for the certified products to meet the interoperability deeming provisions of the physician self-referral exception and anti-kickback safe harbor, respectively.

The Secretary is mindful that the ability of software to be interoperable evolves as technology develops. Consequently, if an enforcement action is initiated for an alleged improper donation of EHR non-certified software, the Secretary would review whether the software was interoperable, as defined in the regulations. The Secretary would consider the prevailing state of technology at the time the items or services were provided to the recipient. As explained in the regulations, the Secretary understands that parties should have a reasonable basis for determining whether the EHR software is interoperable. We therefore indicated that “it would be appropriate—and, indeed, advisable—for parties to consult any standards and criteria related to interoperability recognized by the Department.” Compliance with these standards and criteria, as we explained in the regulations, “will provide greater certainty to donors and recipients that products meet the interoperability requirement, and may be relevant in an enforcement action.”

Based on the changing nature of technological development noted above, the Secretary has accepted these Interoperability Specifications, and intends to recognize them in version 2.0 form in December of 2007, presuming that changes from version 1.2 to version 2.0 are minor and of a technical nature.

He has also delegated authority to ONC to coordinate and oversee the incorporation of these Interoperability Specifications in relevant activities among Federal agencies and other partner organizations, as appropriate.

FOR FURTHER INFORMATION CONTACT:
Judith Sparrow at (202) 690–7151.


Robert M. Kolodner,
Interim National Coordinator for Health IT.

BILLING CODE 4150-24-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Decision To Evaluate a Petition To Designate a Class of Employees at Hanford in Richland, Washington, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employee at the Allied Chemical Corporation Plant in Metropolis, Illinois, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On February 1, 2007, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Atomic Weapons employees who were monitored or should have been monitored for exposure to ionizing radiation while working at Allied Chemical Corporation Plant in Metropolis, Illinois from January 1, 1959 through December 31, 1976, and who were employed for a number of work days aggregating at least 250 work days or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on March 3, 2007, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the Federal Register reporting the addition of this class to SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.