Assessment of Performance-Evaluation Data Derived from Radiobioassay DOELAP.

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Abstract

Part 835 of volume 10 of the Code of Federal Regulations, Occupational Radiation Protection, Subpart B, Section 101, Radiation protection programs, requirement (f) states in part that: Compliance with the requirements of §835.402 (d) for radiobioassay program accreditation shall be achieved no later than January 1,2002. Part (d) indicates that accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Radiobioassay. DOELAP Radiobioassay employs two standards that provide guidance to the facilities and laboratories that desire to gain accreditation in the accreditation process. One is a DOE Technical Standard (DOE-STD-1112-98), The Department of Energy Laboratory Accreditation Program for Radiobioassay. The technical standard, which is designed to accompany ANSI N13.30, provides the technical specifications and assessment criteria to be met by the radiobioassay program requesting accreditation. It also provides general administration and operational information about the performance-testing laboratory that administers the program. The Radiological and Environmental Sciences Laboratory (RESL) is designated as the test laboratory. The second standard is an American National Standard (ANSI), N13.30, Performance Criteria for Radiobioassay, published in 1966. The purpose of this standard is to provide criteria for quality assurance, evaluation of performance, and the accreditation of radiobioassay service laboratories. These criteria include, bias, precision and determination of the MDA. The standard addresses among other things: the accuracy (bias and precision) of direct (*in vivo*) measurements of activity and quantities of selected important radionuclide in test phantoms and indirect (in vitro) measurements of activity and quantities of selected important radionuclides in test samples; minimum testing levels; and methods for determining the minimum detectable amount.

Beginning in 1981, the United States Department of Energy embarked on a program of evaluating and testing laboratories for both direct (in vivo) and indirect (in vitro) radiobioassay measurements. The emerging program has encouraged the development of performance standards by national consensus standards organizations, to evaluate the feasibility and technical appropriateness of the standards for application in DOE operations, and to develop and implement a routing performance testing program. The development of performance standards, blind testing programs, improvements in calibration standards, and site evaluation criteria assisted in this effort.

Data from both the direct and indirect programs will be used to indicate that the analytical ability, in terms of accuracy and precision, of the participating facilities has greatly improved. Data will be used to suggest that the initial criteria of the performance-testing programs should now be revised to more realistically reflect current ability. Currently, the measurement uncertainties are required as part of the data packages, but are not utilized in evaluating the comparison with the

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reference value. Examples will be given utilizing exiting methods that incorporate the measurement uncertainty in the comparison with the expected value.

The indirect (*in vitro*) program of Radiobioassay employs synthetic matrices to conduct the performance-testing aspect of the accreditation process. Alternatives will be proposed to incorporate a more credible approximation of the true matrix. One such adaptation may be the study of dried sewage effluent to more closely mimic human fecal matter. The use of a liquid matrix, real or otherwise, has been limited due to the shipping restrictions placed on the concentration and type of acid necessary to preserve sample integrity. Inter-agency agreements could be explored that would exemption the of the test samples from the existing shipping requirements. A study of sample preservation alternatives is in progress at the testing laboratory and will be briefly discussed.

The program requirements advocate that 'routine' analytical procedures be employed when analyzing the *in vitro* performance-test samples. However, the present procedures used to prepare the performance-test samples do not allow customization for a specific need. This approach forces the participating laboratory to modify or employ procedures that are not used on a routine basis. The paper will present alternative procedures that may be employed in the preparation of the performance-test samples that will provide greater latitude in sample menu choice.

As analytical techniques drive detection limits lower, the temptation to employ those techniques in routine bioassay programs must be evaluated in terms not only of cost or analytical effort, but in terms of worker peace-of-mind. The paper will present examples comparing mass spectrometry with decay counting to explore the benefits and negative aspects of employing such instrumentation. The paper will also review the inclusion of existing technology in the revision of N13.30.