The ISBER Best Practices Self Assessment Tool (SAT): Lessons Learned After Three Years of Collecting Responses

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IN 2009, THE International Society for Biological and Environmental Repositories (ISBER) introduced a Self-Assessment Tool (SAT) to assist individual repositories in determining how well recommended practices found in *ISBER Best Practices for Repositories* (*ISBER Best Practices*) are being followed. The SAT is confidential and allows biorepositories and biobanks to strengthen their practices through the identification of areas in need of improvement. The survey tool consists of 158 questions that are divided into sections or “pages” corresponding to sections of the *ISBER Best Practices*. After completing the SAT, participants receive personalized feedback that includes a “risk-balanced assessment score” that will help them evaluate how closely their current practices conform to the recommendations found in the *ISBER Best Practices*. The score measures the level of risk to the specimens for a given practice, the frequency of implementation of each practice, and the ease with which deviations from the recommended practice can be detected. Participants are notified of the most critical areas in which their responses deviate from the recommended best practices.

Survey results are securely archived at ISBER where the confidentiality of individual respondent responses is strictly maintained. The SAT has been reviewed by the FASEB Protection of Human Subjects Committee and has been deemed exempt from IRB review (FASEB-PHSC-09-03).

Since its inception, over ninety repositories have completed the SAT and eighty additional repositories are represented by responses that are “in progress.” Approximately 50% of the respondents represent repositories within the United States, with the remaining 50% representing repositories in countries throughout the world. Evaluation of completed surveys has identified seven “high priority” areas of repository operations where compliance with recommended best practices fell below 65% (Table 1). Three of these areas relate to equipment operations (temperature mapping of storage equipment prior to initial use, implementation of redundant monitoring systems, and schedules for equipment replacement), three areas relate to quality management systems (standard operating procedures for transferring specimens from a failed unit, policies on retiring collections, and regular audits or reviews of operations), and

one concerns safety (repository representation on a safety committee).

The reasons for low compliance in these areas may reflect budgetary limitations, lack of available technical expertise, lack of training and experience on the part of biorepository staff to recognize the importance of the recommended practice(s), or judgment by the repository that the recommendation is not well-suited for their setting. Two of the main goals of the SAT are to allow repositories to evaluate their own needs for improvement and to provide support for staff seeking funding from stakeholders to improve repository operations, and consequently improve the quality of biospecimens processed, stored and disseminated through those repositories. Feedback obtained from those who have taken the SAT has indicated that almost all have found the analysis helpful in accomplishing these two goals.

ISBER has used the results from SAT responses to identify training needs for attendees of its Annual Meetings & Exhibits.

TABLE 1. AREAS OF NONCOMPLIANCE

Issue	Percent in Noncompliance*
Policies and procedures are in place to evaluate when specimen collections should be retired or culled	45%
A temperature profile of the storage equipment is performed prior to its initial use	40%
A written procedure is in place for transferring samples from a failed unit	50%
The repository employs redundant monitoring systems such that if one fails, a second system is in place	56%
The repository has a plan in place for the timely replacement of equipment	46%
The repository has regular reviews or audits	39%
The repository has a representative that participates in a Safety Committee	47%

*Percent of repositories that do not comply with recommendations in *ISBER Best Practices*.

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For example, at the 2012 Annual Meeting held in Vancouver, Canada, a workshop was presented on evaluating the value of a repository that included information pertaining to when specimen collections should be retired or culled (item 1 in Table 1). The topic of quality issues for biorepositories is also a common theme covered in presentations and workshops at ISBER Annual Meetings & Exhibits. ISBER is also developing a Certification Program for Repository Technicians (CRT) to enhance the technical knowledge base of those working in biorepositories. The CRT will touch on each of the high priority areas identified through the analysis of SAT results.

The SAT has recently been updated and adapted to match changes introduced in the 3rd edition of the *ISBER*

Best Practices for Repositories (DOI: 10.1089/bio.2012.1022). The total number of questions remains the same but the questions have been updated to reflect the new edition. The feedback provided by the updated SAT has been expanded to identify not only the highest risk practices, but also those reflecting intermediate risk. ISBER hopes that the updated SAT will meet the needs of all biorepositories that wish to use it to identify areas for improvement and track improvements over time; use the SAT score as a quantitative quality indicator over time; or simply want to have a one-time compliance assessment. The survey is available at no charge to ISBER members and for a fee for non-members. See www.isber.org/sat/ for additional information.