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Design of a National Indoor-Radon-Measurement Proficiency Program

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Efforts are underway to "privatize" the U.S. national Radon Measurement Proficiency (RMP) program. This program was established and is currently conducted by the U.S. Environmental Protection Agency (EPA), and is intended to assure the performance quality of environmental ^{222}Rn measurements that are performed by commercial vendors of these laboratory services. The extant RMP program has well-known structural limitations in that it is largely based on only two partially fulfilled (of at least four) major elements that are necessary for a more comprehensive measurement quality assurance (MQA) program: viz., the actual measurement-based proficiency tests that are used to periodically evaluate a laboratory's ability to perform accurate measurements under "blind" conditions; and an internal MQA requirement (largely a paper exercise) that is part of the program's application process for the vendor. Both elements are vitally needed, but are insufficient. Equally, the existing program suffers from the absence of consensually-based input from the scientific and user communities in the establishment of program requirements, and from the lack of any control mechanism that can independently affirm the continuing efficacy of the overall program and the specific interactions between the program's systemic components. A review of the underlying philosophy, interactive components, program elements, and necessary requirements for a national MQA system may be timely. The accompanying proposed design for such a system as it might apply to the U.S. radon measurement industry is intended to assist the RMP programs' transition to a "private" entity.

Any successful industry-wide MQA program requires considerably more than mere occasional tests of various measurement laboratories' (or commercial measurement vendors') capability to perform some intended measurements, as evaluated by some testing laboratory and as judged against some defined physical reference standard. This type of performance testing is a critically necessary element, but it is not a sufficient one to establish measurement assurance throughout an industry. Similarly, the mere existence of internal-laboratory MQA requirements (which can in fact be based on just written fictional exercises), without any provision for unbiased audits or certifications, can hardly affirm the quality of a laboratory's output over extended periods of time. Rather, the elements that are necessary for a comprehensive program have been clearly elucidated by Eisenhower, et al. [1-3] at the National Institute of Standards and Technology (NIST). The structure of such programs and identification of the necessary elements are based on over two decades of experience in developing successful programs in a wide variety of disciplines concerned with the metrology of ionizing radiation.

In 1986, because of the perceived "seriousness of the public health threat" resulting from human exposures to environmental radon gas (i.e., ^{222}Rn), the U.S. EPA established a voluntary, nationally-

example, on what constitutes acceptable performance by a testing laboratory or for the interactions between the testing laboratory and NIST.

Thirdly, the development of these operating rules (i.e., the written criteria) may largely reduce to an empty exercise unless there are provisions for independent performance audits that the criteria are being followed at all levels of the MQA system. These periodic performance evaluations should include not only proficiency measurement tests, but also on-site expert assessments and examinations of the services provided to users [3]. Again, the existing RMP program limits the performance evaluations to that of just performing proficiency tests of participating laboratories.

Given the continuing RMP program changes (ranging from changes in what secondary laboratories have performed the proficiency testing to the changes in fiscal support from an originally federally-funded program to one that is ultimately supposed to become fully cost-recoverable), one may, fourthly, note that scant consideration was ever given to the long-term survival of this industry's MQA. The explosive growth in the commercial radon-measurement industry (from almost none 15 years ago to the hundreds of current vendors [5]) undoubtedly contributed to the need for program changes. Yet, the kind of program and structure needed to accommodate the industry should not have been entirely unanticipated since the industry's growth was somewhat predicted [6-8].

Initial directions on the "privatization" of the RMP program [9,10] suggested that EPA had planned to merely "farm out" some of its current activities to a private sector organization without changing any of the program's structure, and while maintaining full operational control over the program's content. If this indeed had occurred (or still does occur), it will represent a tragically lost opportunity to create a full MQA program for the U.S. radon measurement industry.

More recent proposed options by EPA [11] for the "privatization" consist of establishing either (A) one (or more) EPA-approved RMP enterprise(s) whose operation(s) would largely remain under complete EPA oversight and control, or (B) a completely independent "Certification Board" whose operation would be determined by an industry-wide consensus and in which EPA would largely serve as only one of many actors having a clearly vested interest. For reasons eminently delineated above and below, option A is as unsound and flawed as the original, piecemeal "strawman" option which was initially proposed by EPA [10].

Given all of the above conditionals and the widely-varying proposed options that have been and are being floated for a "privatized" RMP program, what might a suitable (and more idealized) alternative be? And what might its structure look like, particularly within the constraints of EPA's proposed option B. Figure 1, adopted with modifications from Inn, et al. [3], illustrates a generalized model that has been employed for several comprehensive ionizing radiation MQA programs, and which could be utilized for the indoor-radon-measurement industry. As indicated, the system consists of four distinct tiers: (i) the primary standards laboratory; (ii) the secondary standards laboratory (or laboratories); (iii) the

The "accrediting organization", as suggested, should be representative of all system interests and should be sufficiently unbiased and independent of the other actors. It should not be dominated or be allowed to be over-ruled by any one player. The criteria established by an accrediting organization may, of course, be subject to particular governmental regulations and requirements. An additional conditional for the accrediting organization is that it should be a formally established and viable entity. Our first concern then, in setting up a radon MQA program, is that we must try to identify what organization (within the radon measurement discipline) would be suitable. Professional organizations or trade associations, like the Health Physics Society (HPS), or the Conference of Radiation Control Program Directors (CRCPD), or the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), or the American Association of Radon Scientists and Technologists (AARST), or comparable others, are the most likely candidates. Why? They are existing, chartered organizations with a degree of credibility. Their membership has an evident vested interest in the success of any radon MQA program and represents most segments of the involved actors. An entirely new entity (e.g., the EPA proposed "Certification Board"), if adequately chartered, may equally be appropriate. Irrespective of the particular choice, the chosen entity would have to establish a new, and clearly defined, accrediting structure within its existing organization . Details of this structure and its operation (and funding) must be achieved at by consensus of the system's actors themselves. Precedents exist for how this can be achieved. The steps, simplistically, would consist of: (i) an initiating effort by the leadership of a suitable organizing entity to establish the industry-wide MQA; (ii) ground work by a fully-representative ad hoc committee to flesh out the accrediting structure and operating rules; and (iii) chartered formalization (and subsequent actualization) of the established MQA structure. To be truly effective, the accrediting organization should not concern itself with establishing criteria, evaluating performance and "accrediting" only the secondary laboratories (which is often done in some MQA programs) or the measurement-vendor laboratories. Rather, they should establish criteria and evaluate the performance between each link in the measurement chain; i.e., for the interactions between the first- and second-tier laboratories, between the second- and third-tier laboratories, and between the third-tier laboratories and ultimate users.

The first two tiers of the MQA structure and their required interactions should be somewhat obvious. The primary standards laboratory, at the apex of MQA program's hierarchial structure, is NIST. It maintains a primary national measurement standard for ^{222}Rn activity [12] and disseminates this standard to any secondary laboratories. The two EPA laboratories at Montgomery, AL and Las Vegas, NV presently serve as the secondary laboratories that perform the proficiency testing of the commercial measurement vendors. Initially, during the first few years of the EPA RMP program, the Environmental Measurements Laboratory (EML) of the U.S. Department of Energy (USDOE) served as the secondary testing laboratory. Although interactions between EML and NIST were not formalized as part of the initial stages of the RMP program, the EML is one of the premier radon-measurement laboratories in the world and has had nearly 50 years of cooperative dealings with NIST on ^{226}Ra and ^{222}Rn measurement intercomparisons. The EML maintains a primary ^{222}Rn calibration capability that is based on the use of national ^{226}Ra standards with a measurement system [13] that was modelled after the NIST primary standard [12]. Parenthetically, it may also be noted that the EML, as the USDOE MQA center for radon gas and its

could be one of providing independent audits and oversight. A revised model having this structure is given in Figure 2. As shown, the EPA laboratories could be set up and used to independently check the measurement performance between each system tier. They could, if they found problems, recommend or require (by regulatory authority if they possess it) system changes on the part of the accrediting organization. As indicated earlier, I would foresee that the EPA would have a very strong voice in establishing the system's operating criteria. This would insure their needs in maintaining a degree of control over the quality of radon measurements being made in the U.S. For internal system consistency, the EPA laboratory should maintain the identical kind of interactions with NIST that would be maintained between the designated proficiency-testing secondary laboratory and NIST. Again, there are precedents. For example, the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services has regulatory authority over the production and proper use of radiopharmaceuticals. It performs extensive audits of the manufacturer's practices. Its radionuclidic metrology laboratory in Winchester, MA occasionally conducts independent, "blind" evaluations of the measurement performance of manufacturers. At the same time, this FDA laboratory is a participating member of the measurement assurance program for the radiopharmaceutical industry (jointly operated, under a cooperative research and development agreement, by the Nuclear Energy Institute and the NIST [18]). The multiplicity of FDA roles, in this case, is revealing and must be emphasized: the FDA imposes rigorously-enforced regulations on the radiopharmaceutical industry; it actively participates in the industry's established MQA system; and it independently audits the measurement performance of the industry's participants. Perhaps an analogous role for the EPA would be most suitable for any type of privatized, industry-based radon MQA system.

The necessary linkage and performance criteria between the secondary-laboratory tier and the third-tier measurement vendors could largely be modelled after that used in the existing RMP program. Any deemed modifications, such as to strengthen compliance requirements, to provide mechanisms and incentives for self-correcting observed measurement biases, to establish provisions for on-site assessments, or to minimize burdensome, paper-work trivialities, could be addressed by the accrediting organization in developing the new operating rules. One advantage in going to privatized secondary laboratories would be that we could then dismiss, once and for all, the pretension that the proficiency testing laboratories are <u>not</u> providing "calibrations" through the RMP program. Everyone even remotely familiar with the system knows that they do. It may be denied or called by some other euphemism, but the current RMP program is undoubtedly the largest provider of ^{222}Rn measurement calibrations in the U.S. The provision of initial and continuing calibrations by a secondary laboratory is a natural and logical adjunct to its proficiency testing role. This is exactly what occurs in the interactions between the primary and secondary laboratories. Why shouldn't it equally be done between secondary and tertiary laboratories? Other logical functions of the secondary laboratory would be to provide their user community with other services (on a cost recoverable basis) like evaluating measurement protocols or testing measurement devices. The differing needs of the participating laboratories will require a participation fee structure that is based on the level of services (and its true costs) obtained by participants from the program.

The next step down on the tiered hierarchy is the most curious. The interactions between the

price increment needed to support the industry-wide MQA system can be obtained by division of the total number of ^{222}Rn measurements made by the participating laboratories into an estimate of the total cost needed by the accrediting organization to support the system. Related to these economic fundamentals is the issue of whether the demand for ^{222}Rn measurements in the U.S. can really support the number of existing vendors. I personally doubt it. Is it an apostasy to suppose that perhaps some of the current industry's woes, including the absence of a viable MQA system, are a result of depressed prices on the part of technically-unsound and financially-weaker vendors? I rather suggest that it is the industry's quiddity.

Parts of the proposed design and much of the above discussion will undoubtedly be controversial with certain actors in the ^{222}Rn measurement community. The views are admittedly subjective, but are founded on a fair degree of experience with successful MQA programs. It is intended to serve as well-disposed advice to the U.S. radon measurement industry. Hopefully, it will provoke serious thought on one possible direction that could be taken, lest that the industry remains captive to an incomplete MQA system that was externally imposed and controlled. Replacing the existing RMP program with a strong, industry-initiated and -based MQA system will not be an easy task. It will require, as a first giant step, a devoted effort on the part of the industry's leaders to identify a suitable accrediting organization and to establish the necessary *ad hoc* framework within it that will begin to work out the operating details. In the ideal, the finalized accrediting body will be a fully-representative voluntary association that is financially self supporting. The organizers must actively seek participation by all members of the ^{222}Rn measurement community (this includes not just commercial industry members, but also all interested federal and state health-protection agencies, relevant supporting laboratories like NIST and those of the EPA, and even concerned citizen and consumer groups), and provide sufficient incentives for their participation. Anything less is unlikely to support and promote vigor within the industry, or to assure the integrity of measurements that are intended to protect the health of our citizens.

[16] E.L. Sensintaffar and S.T. Windham, Calibration of Scintillation Cells for Radon-222 Measurements at the U.S. Environmental Protection Agency, *J. Res. Natl. Inst. Stds. Tech.* **95**, 143-145 (1990).

[17] J.T. Cessna, R. Collé, P.A. Hodge and J.M.R. Hutchinson, Relation of National Standards to Proficiency Testing of Commercial ^{222}Rn Measurement Vendors in the U.S., *to be published* (1997).

[18] D.B. Golas, USCEA/NIST Measurement Assurance Programs for the Radiopharmaceutical and Nuclear Power Industries, *Proceedings of the Workshop on Measurement Quality Assurance for Ionizing Radiation*, pp.191-206, Pacific Northwest Laboratory Report PNL-10076, U.S. Department of Energy CONF-9303220, 1993.

Figure Captions:

Figure 1. A generalized model of an effective MQA system.

Figure 2. A revised model of a MQA system for the U.S. radon measurement industry, illustrating the independent oversight and auditing role of the EPA.

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is a research chemist in the Radioactivity Group of the NIST Physics Laboratory (Ionizing Radiation Division). He has nearly 20 years of experience with radon measurement issues in the U.S., and has been closely associated with the commercial radon measurement industry from its inception. Some of his primary responsibilities at NIST have involved maintaining the national standards for ^{226}Ra and ^{222}Rn activity, and developing and disseminating new transfer standards and measurement methodologies for them. He also spent nearly a decade with the NIST Office of Radiation Measurement in helping to design and implement MQA systems. He has served on or advised virtually every national radon subcommittee, federal inter-agency radon working group, informal radon measurement steering committee, or *ad hoc* radon delegation (composed whenever three or more "radon experts" gathered in the same room!) that was constituted in the past 15 years, including the informal steering group that originally advised the EPA on the establishment of its RMP program.

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Figure 2. A revised model of a MQA system for the U.S. radon measurement industry, illustrating the independent oversight and auditing role of the EPA.