

**Colorado Radiation Advisory Committee (RAC)
June 2, 2016 Meeting Minutes**

I. CALL TO ORDER	RAC Chair Tom Johnson called the regular meeting to order on June 2, 2016 at 1:10p.m., in Conference Room A5A, Building A, at the Colorado Department of Public Health and Environment (CDPHE) main campus.
Agenda	The agenda emailed in May 2016 was used.
Introductions	<p>Radiation Advisory Committee (RAC) members and Radiation Control Program staff introduced themselves.</p> <p>RAC members in attendance: Steve Brown, Tom Johnson, Vicki LaRue, Craig Little, Robert Ryu, Riad Safadi, and Jennifer Stickel.</p> <p>The members present constituted a quorum.</p> <p>RAC member(s) absent: Jim Burkhart (excused), Vinod Ravindran (excused)</p> <p>Radiation Control Program staff in attendance: Linda Bartish, James Grice, James Jarvis, Chrys Kelley, Jennifer Opila, and Brian Vamvakias.</p>

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<p>II. SELECTION OF VICE-CHAIR</p>	<p>The RAC voted by written ballot and elected Jennifer Stickel to serve as Vice-Chair of the RAC through the end of 2016.</p> <p>The written ballot for the Vice-Chair included members Jim Burkhart and Jennifer Stickel. (Note: the election for vice-chair was deferred from the March 31, 2016 RAC meeting by a vote of RAC members.)</p>
<p>III. Program Updates</p>	
<p>A. Radiation Program update</p>	<p>Jennifer Opila provided an update on the Radiation Program.</p> <p>Jennifer gave an an update regarding the proposal by Black Range Minerals (BRM) to conduct ablation technology activities in Colorado at an existing uranium mine site.</p> <ul style="list-style-type: none"> - Over the past several months, a number of stakeholder meetings were held throughout Colorado to gather input and feedback regarding the BRM ablation project. Meetings were generally well attended, with approximately 6 attending the Denver meeting, approximately 40 attending the Canon City meeting, and approximately 25 attending the Naturita meeting. A number of these attendees participated by phone. The most comments were received at the Canon City meeting. Comments varied depending upon location of the meeting with those in Canon City generally opposed to the project/technology and supporting a more rigorous regulatory process while those in Naturita were generally in support of the project and likened it more to mining activities and generally favored a less rigorous regulatory process. <p><i>Member Steve Brown** commented that he believes that the process is similar to mining and that it falls under the "unimportant quantities" of source material contained in the regulation. [**Steve Brown disclosed that he is a consultant to BRM and that he completed the radiological assessment for the BRM ablation project on behalf of BRM.]</i></p> <p><i>Member Craig Little inquired as to where the resulting feed materials (product) would go after processing?</i></p> <p>Member Steve Brown indicated that the produced materials would possibly go to an Energy Fuels facility or possibly another mill, depending upon timing.</p>

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	<p><i>Member Tom Johnson asked what the anticipated radiological affects would be?</i></p> <p>Jennifer Opila indicated that these are outlined in the BRM project documents on the Department website. Jennifer Opila indicated that the initial BRM approach to the project was to treat it as more of a legal issue without presenting the radiological risks. This approach was deemed to be unacceptable by the Department, and additional risk related information was requested from BRM.</p> <p>No written program update was available for the meeting.</p>
B. Radioactive Materials (RAM) Unit update	<p>Jim Grice provided an update on the activities of the Radioactive Materials Unit.</p> <p>Jim discussed:</p> <ul style="list-style-type: none">- The fact that several new staff is coming on-board in the next few weeks.- A new Ge-68/Ga-68 generator is being marketed to medical licensees. This device is a bit different in a variety of ways in that the generator is used by the end-user medical facility. Although some facilities still receive generators to make their own radiopharmaceuticals, most receive unit doses from the nuclear pharmacies. The generator - which is used to produce a brain imaging agent - will be used by the end user medical facility. The device presents some unique regulatory issues. <p><i>Member Riad Safadi made the statement that when a new drug is developed, all (radionuclide) contaminants must be identified.</i></p> <p>Jim Grice responded/concurred that yes that is correct.</p> <p><i>Member Vicki LaRue inquired as to what type of quality control was developed during the Investigational New Drug (IND) phase of approval as a drug?</i></p> <p>Jim Grice responded that an NRC and Agreement State working group is looking into this.</p> <p><i>A RAC member inquired as to what is meant by the term "breakthrough" (which came up during the discussions)?</i></p> <p>Jim Grice responded that breakthrough is the term used for</p>

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	<p>the contaminant(s) that can carry through to the final drug product. The regulations specify how much breakthrough is permitted.</p> <p><i>Member Steve Brown inquired as to the difference between the terms "radiochemical" and "radiopharmaceutical"?</i></p> <p>Jim Grice responded indicating that a radiochemical typically cannot be administered directly to a patient. Radiochemicals cannot also be used by/under the supervision of the authorized user (physician).</p> <p>***</p> <p>Linda Bartish provided a presentation on the general licensing (GL) program.</p> <p>Jennifer Opila emphasized that our GL program goes beyond the minimum requirements for regulating GL materials.</p> <p>Further details may be found on the attached radioactive materials unit summary and general license presentation.</p>
<p>C. X-Ray Certification Unit update</p>	<p>Brian Vamvakias provided a summary of the x-ray certification unit activities.</p> <p>Refer to the written update for further information.</p>
<p>D. Radon Program</p>	<p>Chrys Kelley provided an update and summary on the activities of the Radon program.</p> <p>Chrys discussed:</p> <ul style="list-style-type: none"> - Her active participation on a number of boards and committees, including the National Radon Proficiency Program (NRPP), the Colorado Cancer Coalition committee, and the state lung cancer task force. Chrys has also been active in giving presentations at town hall meetings sponsored by one of the state senators. Chrys discussed the major elements of the Low Income Radon Mitigation Assistance (LIMA**) Program that was initiated in the Colorado legislative session and finalized through house bill HB 16-1141. It is estimated that the program will have sufficient funding to help approximately 100 homeowners mitigate their homes. <p>**NOTE: The LIMA Program has been subsequently named the LIRMA Program.</p>

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	<p><i>RAC Member Steve Brown stated that he understands that about 40-50% of homes in Colorado have radon levels that exceed 4 picoCuries per liter - is this correct?</i> Chrys Kelley indicated that yes that is correct.</p> <p><i>RAC Member Riad Safadi inquired as to how the program will help ensure that there is not abuse in this program and / or whether there is false information being provided?</i></p> <p>Chrys Kelley indicated that only nationally certified contractors will be eligible to become part of the program. Any of these contractors caught falsifying information or trying to take advantage of the system will be reported to the national certifying agencies which could result in suspension or revocation of their certifications. Additionally, Chrys will be the primary person tracking and reviewing applications, mitigation plans, and installations which will allow the program to look for any unusual trends or activities that could indicate wrongdoing.</p> <p><i>RAC Member Steve Brown asked whether there was separate funding for the public outreach program?</i></p> <p>Chrys Kelley stated that there is approximately \$180K total, but \$100K would be devoted to the LIMA program, with the rest of the funding going toward the general outreach program.</p> <p>As part of the program review, it was recommended by the RAC members that the formal definition for "single family home" be reviewed for consistency with its use in the proposed regulation.</p> <p>***</p> <ul style="list-style-type: none">- Chrys indicated that the State Indoor Radon Grant (SIRG) funding from the US Environmental Protection Agency (EPA) was recently approved. <p>No written update was available for the meeting.</p>
E. Regulations / Special Projects update	<p>James Jarvis provided an update and summary on the activities and status of regulatory activities.</p> <p>James:</p> <ul style="list-style-type: none">- Discussed the approval by the Board of Health of Part 16 (well logging), and Part 19 (irradiators) at its May 2016 meeting. The rule will move to a rulemaking

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	<p>hearing in July, where final approval is expected;</p> <ul style="list-style-type: none"> - The Part 6 (x-rays in the healing arts) rule development has slowed due to more time need to develop the proposed radon regulation and its short timeline requirements. The original rulemaking schedule had Part 6 going before the board of health in the fall. Instead, this rule will be moved to the 2017 calendar to allow for outreach and interaction with stakeholders. - The draft Part 21 (Low Income Radon Mitigation Assistance (LIMA) Program) regulation was reviewed and discussed. The process outline and draft rule (Draft A dated 05/24/16) and handout provided during the meeting was discussed. - Reviewed and discussed the updates to the RAC Bylaws to address several minor changes needed. The changes proposed included aligning the appointment period written in the current bylaws (3 years) with the actual RAC member appointment periods issued by the Governor (4 years), along with minor typographical and clarifying and wording changes. The RAC members in attendance voted (by show of hands) to approve the proposed changes to the bylaws as written. <p>Refer to the regulatory update, draft Part 21 rule, and draft bylaws for further details and information.</p>
F. Subjects for future discussion	None
G. Adjourn	The meeting adjourned at approximately 3:30 p.m.
Next RAC Meetings:	<p>Remaining 2016 RAC meeting dates: September 29, 2016 December 1, 2016</p>

Attachments:

1. Colorado Radiation Advisory Committee Agenda for June 2, 2016, as emailed in May 2016 (1 page)
2. Ablation Technology Regulatory Process summary page (1 page)
3. Radioactive Materials Unit update (1 page)
4. Presentation on generally licensed (GL) devices (7 pages)
5. X-Ray Certification Unit update (2 pages)
6. Radiation regulations update (2 pages)
7. LIMA Process outline (1 page)
8. Part 21, Draft A (dated 05/24/16) regulation (4 pages)
9. Proposed (draft) changes to the Colorado Radiation Advisory Committee (RAC) Bylaws (8 pages)

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Following incorporation of any requested changes, the Radiation Advisory Committee meeting minutes for May 2, 2016, were approved via email by a quorum of members September 8-19, 2016.



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Department of Public Health & Environment

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**COLORADO RADIATION ADVISORY COMMITTEE
MEETING AGENDA**

Thursday, June 2, 2016 1:00 P.M., CDPHE - Building A
Conference Room A5A (Board Room)

REGULAR MEETING

1:00 PM	I. CALL TO ORDER, INTRODUCTIONS, AGENDA ADDITIONS / CHANGES
1:05 PM	II. Selection of new RAC Vice-Chair for 2016 - re-vote/continuation from 03/31/16 Meeting (10 minutes)
	III. PROGRAM UPDATES
1:15 PM	A. Radiation Program update - James Jarvis/Jim Grice (20 minutes)
1:35 PM	B. Radioactive Materials Unit update - Jim Grice (30 minutes) 1. General licensing program overview - Linda Bartish
2:05 PM	C. X-Ray Certification Unit update - Brian Vamvakias (15 minutes)
2:20 PM	D. Radon Program update - Chrys Kelley (30 minutes) 1. Review of draft Part 21 (Low Income Radon Mitigation Assistance Program) Regulation
2:50 PM	E. Regulations/Special Projects update - James Jarvis (20 minutes) 1. Proposed updates to RAC Bylaws (postponed from 3/28 meeting)
3:10 PM	F. Subjects for future discussion
~3:15 PM	G. ADJOURN
	2016 RAC Meetings: - July 28, 2016 - September 29, 2016 - December 1, 2016

NOTE: all times, topics, and future meeting dates are subject to change





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Ablation Technology Regulatory Process

In July 2015, Black Range Minerals submitted information to the department regarding their ablation technology and asked the department to make a determination on how this technology would be regulated under the *Colorado Rules and Regulations Pertaining to Radiation Control*. The department requested additional information from Black Range in August 2015 and received a response from Black Range in April 2016.

The department is seeking to evaluate how it should regulate this new technology to properly manage the risks to the public and the environment. In order to achieve this goal, the department is evaluating how this technology fits into its current regulatory framework and seeks inputs from all stakeholders to help us make these decisions. Some possible options include:

- No radioactive materials license
- General radioactive materials license for the possession of source material involved in mining operations
- Specific radioactive materials license for source material
- Part 18 radioactive materials license for Uranium processing (not milling)
- Source material milling radioactive material license
- New regulatory category

The department also seeks input as to what kind of application information, financial assurances, and public process would be appropriate if a license will be required. All material for review can be found on the CDPHE Ablation Process - Black Range Minerals web page: (<https://www.colorado.gov/pacific/cdphe/ablation-process-black-range-minerals>).

Public comments on the above issues will be accepted through July 8, 2016 and can be sent to:
Jennifer Opila, Radiation Program Manager
Colorado Department of Public Health and Environment
4300 Cherry Creek South Drive
Denver, CO 80260
jennifer.opila@state.co.us

Additionally, the department will collect public comments at three stakeholder meetings:

- **Thursday, May 26, 2016 - Denver** - 6:00 p.m. - 8:00 p.m.
Colorado Department of Public Health & Environment
4300 Cherry Creek Drive South, Sabin-Cleere Room, Building A
- **Tuesday, May 31, 2016 - Cañon City** - 6:00 p.m. - 8:00 p.m.
Quality Inns & Suites - 3075 E. US 50
- **Wednesday, June 1, 2016 - Nucla/Naturita** - 6:00 p.m. - 8:00 p.m.
Rimrock Hotel - 123 Main Street, Naturita
- **Wednesday, June 22, 2016 - Denver** - 6:00 p.m. - 8:00 p.m.
Colorado Department of Public Health & Environment
4300 Cherry Creek Drive South, Sabin-Cleere Room, Building A

To participate in any of the public meetings by telephone please call 1-877-663-3863. Enter Conference ID: 6923435 when prompted. The telephone lines will open at 5:55 PM. The call-in lines are available on a first-come, first-served basis.



Radioactive Materials Unit

Project Status 6/2/2016

Staffing:

- We have two new staff members coming on in the next two weeks. Will be a lot of training for these individuals.

Licensing/Compliance

- Part 22: Physical protection of Category 1 and Category 2 quantities of material. The old Increased Controls have been replaced by this new regulatory structure.
 - We have completed a handful of inspections and there has been few issues with non-compliance. We will see how this progresses over time since quite a few of the changes will not affect normal operations immediately.
- Germanium-68/Gallium-68 generator: PET material/radiochemical
 - Ga-68 can be eluted using various concentrations of HCl. Radiochemical vs. Radiopharmaceutical
 - New drug: Dotatate, Neuroendocrine tumor detection
 - Ge-68 breakthrough and breakthrough testing questions
 - ⁶⁸Ga-DOTATATE PET scan can dramatically improve the spatial resolution and lesion detectability compared to past methods. Approved by the FDA yesterday. (Netspot is marketed by Advanced Accelerator Applications USA, Inc.)
 - NRC has working group looking into the technical/licensing issues

Escalated Enforcement

- Nothing new.

Incidents, emergencies, etc.

- Received an allegation regarding a hospital diagnostic program – both X-ray and Materials. Was investigated jointly and the complaint was determined to be unfounded.
- Complaint from member of the public regarding water treatment residuals and potential cancer effects. Coincided with a press inquiry. Multiple division response.
- Member of the public sent a photo of a density gauge unsecured in the back of a pickup while entering the highway. NOV issued.
- SIR spheres misadministration. Clogged catheter.
- HDR misadministration. Source transfer tube disconnect.

General License Devices

- **General license devices are acquired by a person or company.**
 - No license is issued in Colorado for a person or organization that acquires, uses, or possesses a generally licensed device.
 - Device must be received through an authorized transfer by the device manufacturer/distributor, or by change of company ownership where device remains in use at a particular location.
- **Notification of the transfer to the regulatory authority is required.**
- **Any receipt of a device through an unauthorized means requires the company to contact the regulatory authority immediately.**

Thermo Density Gauge



Ion Mobility Spectrometer



Dust Monitor



Static Eliminator

The Radioactive Materials Unit

General License

- **The activity of radioisotope and use shown in sealed source and device registry determines if the device is regulated under a general license.**
- **Manufacturer or distributor Reporting Requirements set in Part 3**
 - Quarterly reporting to regulatory agency is required
- **Reports received include:**
 - transfer or disposal of devices
 - identification of the device by manufacturer's name
 - model number, serial number, name, address
 - license number of recipient,
 - date of transfer in the report.
- **Report change of ownership of the facility (when device remains in use at a particular location).**
 - the company name and model number, serial number, name and address of the transferee, and name of the responsible individual of the transferee.

Uses for General License Devices



Devices Registered in Colorado:

- **479** devices designed and manufactured to detect, measure, gauge, or control thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or ionizing air, or for producing light (e.g., gas chromatograph units; moisture/density, fill level, insertion and transmission gauges; static eliminators and ion generating tubes).
- **6,533** self-luminous Tritium exit signs

Registry Process for Devices



- Data is kept in the general license database. Notifications are sent to the end user (general licensee) annually for changes and verification.
- New companies are contacted to verify data provided in the manufacture's quarterly report. Then sent a letter, and inventory report requesting authentication of the data.
- The data provided by the manufacture for exit signs is often inaccurate. The data shows development companies, subcontractors, electricians, and installers are listed as the end user (general licensee), but are really "middleman".
- Determining responsible party for the devices may take several attempts and lots of time.

Annual Notification



- Annual notifications are sent to all active registrants in the general license database. The purpose is to provide the owner of the of the GL device information that is vital in understanding the Colorado Regulations for General License devices.
- In 2015 over 1300 general license records were reviewed. The findings identified that companies were unaware of regulations surrounding the responsibility for maintaining records, showing receipt of devices or transfer and disposal of all devices.
- The lack of tracking from installation to disposal occurs most often upon change of management or new staff being assigned to the devices.

Reports of Lost/Abandoned/Damaged Exit Signs

- **After Wal-Mart Stores said it could not find 15,000 exit signs in 2006, the NRC began requesting any buyer of more than 500 signs — to inventory them and report whether any could not be accounted for. Results indicated dozens of businesses, government agencies and schools nationwide reported losses to federal regulators.**
- **This demonstrated that organizations may not be fully aware of the regulatory requirements for owning these signs and that they are also subject to NRC or state inspection and enforcement action (including fines) for violating requirements. No fines are currently being issued in Colorado.**
- **In 2006 the Radioactive Materials Unit began sending notifications to all companies with exit signs. Fees are charged for any company in possession of 4 or more exit signs and other generally licensed devices.**
- **Out of 896 entities registered under the general license category in Colorado over 433 companies possess Tritium exit signs**
- **In 2015, Colorado reported to the NRC, 19 cases of lost, abandoned or destroyed exit signs.**

Challenges for 2016 & Beyond

- Electronic annual reporting began this year (2016).
 - Should help to streamline our efforts and data collection
- Efforts to reach non-responsive companies is forever challenging.
- Discovering distributors or transfers of general license devices and non-reporting is also challenging.

RAC Meeting June 2, 2016

X-Ray Certification Unit Status

Staffing

- An EPS I position was created to expand the compliance enforcement efforts of the Unit. A candidate has been chosen and we expect that person to start in June.
- A Temp Aide position is open to help with the conversion of our paper documents to electronic documents, among other duties.
- Christine Irving has announced her retirement and will be leaving us after 30 years of service at the end of July.

Regulatory Changes

- Currently reviewing CRCPD SSR Part H, which covers the use of various x-ray machines used in the “healing arts”. This part regulates medical, dental, chiropractic, podiatric and veterinary uses of x-ray machines when the machines are being used to perform diagnostic exams on living patients. Part 6 in the Colorado *Rules and Regulations Pertaining to Radiation Control* is the analogous section that is being changed to incorporate recent changes to Part H. The changes could affect the following areas:
 - Credential requirements for users of fluoroscopic machines. Requests to include Physician Assistants and Nurse Practitioners in the “approved” list have been received from our stakeholders. There is an ARRT test available to state agencies that covers the safe use of fluoroscopic machines developed for the PA and NP personnel.
 - Facilities with CT or interventional fluoroscopic machines may have to create a Radiation Protocol Committee to review exposure levels to patients. There is also a suggested requirement that all CT facilities be certified by an accrediting body.
 - The structure of the CT regulations may change to incorporate cone beam-type machines.
- A company that wants to market a radiation therapy machine to dermatologists does not agree that the dermatologists should have the training required by Part 24 for physicians supervising the operation of a radiation therapy device. There are also certain administrative requirements for facilities using a radiation therapy machine that this company does not feel are necessary for the model they are selling. This machine is in use at one oncology suite in Colorado.

Process Improvement

- We are six months into using our new database. Some “bugs” are being worked out to make this database track violations similar to the defunct FoxPro system.
 - A system to generate notices is being worked out so that we can send notices by email.
 - The online registration process has gone through some changes and that has made it a challenge to get email contact information into the database.

- X-ray is working on a paperless process for receiving and sending correspondence to our registrants. Almost all of x-ray machine certification reports are received as Adobe documents and are processed electronically. The registration of QI's and Service Companies will be paperless soon. The next group of registrants to change over are the registered operators such as the Limited Scope Operator, Colorado CT Operator and Provisional Mammography Operator.
- A Compliance Plan is being revised to include an additional field inspector. The initial focus will be on overdue machines. The scope of the Compliance Plan will include QI's and Service Companies, as well as facilities.

Escalated Enforcement/Emergencies

- Thankfully, none to report

Recent News

- CRCPD trip to Lexington, KY. Three staff were able to obtain 15 hours of mammography-specific training to satisfy the requirements to be an FDA MQSA inspector. Parts of the conference covered topics related to x-ray machines such as patient dose tracking and new technology development.

Radiation Regulations Update 06/02/16 RAC Meeting

PARTS 16, 19 RECAP & UPDATE

- During the January 2016 RAC meeting, the committee reviewed and discussed the proposed changes to Part 16 (Well Logging) and Part 19 (Panoramic Irradiators).
- A 45 day stakeholder meeting was held in the February-March timeframe - only 1 comment received.
- During the May Board of Health meeting, the Board approved our request for a rulemaking and a rulemaking hearing was set for July 20.

PART 6 (X-Rays in the Healing Arts)

- Part 6 rule being updated for consistency with SSRCR model regulation Part "F" (2015 revision).
- Internal development has slowed due to focus on the Radon Reg, but is still working
 - Internal development needs to be completed before we bring it to the RAC (or stakeholders)
- Formal rulemaking/BoH process originally planned for this fall, will be moved to spring 2017
 - We are considering the need for some type of survey to gather information and/or a possible stakeholder focus group
 - We may begin some stakeholder processes this fall

PART 21 (New Radon Mitigation Assistance Regulation)

- Rule schedule:
 - Due to the wording in HB 1142, we are on a short timeline with this rule - our attorney's indicated we need to have a rule on the books by January 1, 2017.
 - Draft sent to RAC last week (May 24) - comments requested by 6/6
 - June 26 - stakeholder meeting scheduled - 5-7:30pm here at CDPHE.
 - Call in capability will be available
 - To be sent for public comment ~June 10 through July 11
 - Request for rulemaking before the BoH on August 17 with rulemaking hearing on October 19
 - Under this schedule, the rule would become effective late Dec
- The initial draft rule was modeled after a CDPHE regulation for an HIV grant program.
- Just received comments from our Board of Health Administrator. We are evaluating them for possible incorporation into the rule, but anticipate some changes to the draft before we send for public comment:
 - Possible incorporation of a definition for "homeowner";
 - Addition of basic Colorado residency statement;
 - May add some specific timelines:
 - 30 days for department to respond to an application;
 - 30 days for applicant to respond in the event info is missing;
 - 60 days for contractor to complete the work;
 - Add a requirement that testing be completed within 12 months of the application date;
 - Expand the content regarding requirements for contractors
 - Rule is currently heavier re: homeowner/applicant requirements
 - There is currently a value of \$2500 specified for the maximum cost of the system - this will likely change to \$1500 to coincide with the fiscal information that went with the bill during the legislative process.
 - The provisions in the applicant appeal process may be reduced;
 - Reporting requirements will change - with information available from us and/or posted on the web rather than presented to the Board of Health.
 - We may need to have further detail that is currently in the application process/policies - tbd

CONTRACTOR PROCESS:

- ➔ Contractor applies to be a LIMA contractor (must be certified by national organization, other requirements)
- ➔ Contractor is listed as a LIMA eligible contractor to perform mitigation system installations under the program

HOMEOWNER PROCESS

- ➔ Homeowner does radon test - results > 4 pCi/L
- ➔ Homeowner applies to LIMA program submitting a variety of documents (application form, test results, IRS tax forms, HOA approval, etc.)
- ➔ LIMA Program reviews application and grants or denies approval
- ➔ If granted, homeowner sent a list of eligible contractors to choose from
- ➔ Contractor visits home, assembles mitigation plan
- ➔ LIMA Program reviews the mitigation plan and approves or denies plan
- ➔ Contractor signs statement of work agreeing to terms of the program
- ➔ If approved, mitigation system is installed
- ➔ Contractor submits evidence of installation (photo's, etc.) to LIMA Program
- ➔ Homeowner performs post-mitigation radon test and submits results to LIMA Program
- ➔ LIMA Program issues payment directly to contractor

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Hazardous Materials and Waste Management Division

3 RADIATION CONTROL - COLORADO LOW INCOME RADON MITIGATION ASSISTANCE (LIMA)
4 PROGRAM

5 6 CCR 1007-1 Part 21

6 *[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

7 _____

8 Adopted by the Board of Health October 19, 2016

9 Part 21: COLORADO LOW INCOME RADON MITIGATION ASSISTANCE (LIMA) PROGRAM

10 21.1 Definitions

- 11 A. "Board" means the State Board of Health.
- 12 B. "Certified test kit" means a radon test kit (and analysis) that is certified by the National Radon
13 Proficiency Program (NRPP) or the National Radon Safety Board (NSRB).
- 14 C. "Certified radon measurement contractor" means a contractor that is certified to conduct testing
15 by the National Radon Proficiency Program (NRPP) or the National Radon Safety Board (NSRB).
- 16 D. "Colorado Low Income Radon Mitigation Assistance Program" (LIMA) means the assistance
17 program created to address local community needs through an assistance process established
18 pursuant to Section 25-11-114, C.R.S. administered by the Hazardous Materials and Waste
19 Management Division (HMWMD) at the Colorado Department of Public Health and Environment
20 (CDPHE).
- 21 E. "Conflict of Interest" consists of one or more the following conditions:
- 22 1. Any individual who has a personal or financial interest that could reasonably be perceived
23 as an interest that may influence an individual in his or her official duties.
- 24 F. "Department" means the Colorado Department of Public Health and Environment or CDPHE.
- 25 G. "Division" means the Hazardous Materials and Waste Management Division.
- 26 H. "Financial interest" means an interest held by an individual which is an ownership or vested
27 interest in an entity or employment, or investment interests, or a prospective employment for
28 which negotiations have begun, or a directorship or officership in an entity, or immediate family
29 members.
- 30 I. "Fiscal year" means the period commencing July 1 of a calendar year and concluding June 30 of
31 the following calendar year.
- 32 J. "LIMA eligible certified radon mitigation contractor" means a company that has applied for
33 eligibility to the LIMA program and has been approved to participate in the program.

34

35 **21.2 Program goal**

36 The assistance program is created to address local community needs by funding the installation of radon
37 mitigation systems and post-installation radon testing in owner-occupied low income homes showing
38 elevated levels of radon. The program is intended to reduce the risk from cancers caused by radon in
39 single family owner occupied homes in Colorado.

40 **21.3 Criteria for mitigation system assistance**

41 The following contains the criteria under which homeowners may receive assistance (funding) for the
42 installation of radon mitigation systems under the Colorado low income radon mitigation assistance
43 program:

- 44 A. The home must be a single family, owner-occupied home.
- 45 B. The homeowner applicant must be a low-income household and meet the low income criteria in
46 accordance with the most current U.S. Housing and Urban Development (HUD) statewide income
47 limits for Colorado as posted on the HUD website.
- 48 C. Assistance with mitigation system installation will be provided for homes with radon levels
49 exceeding 4.0 picocuries per liter (4.0 pCi/l) as tested using a certified test kit or certified radon
50 measurement contractor. Initial radon testing will not be paid for or reimbursed under this
51 program.
- 52 D. Homes with mitigation systems currently installed are not eligible for mitigation assistance funding
53 or reimbursement under this program.

54 **21.4 Applying for assistance**

- 55 A. Applicants (homeowners) seeking funding to pay for radon mitigation and post-mitigation radon
56 testing shall follow the LIMA Policy and Procedures Manual and complete the LIMA Homeowners
57 Application form H1 found on the radiation program website.
- 58 B. In addition to any other penalty imposed by law, any applicant who knowingly or intentionally
59 provides false information to the department when applying for assistance shall be ineligible to
60 receive any future funds under these rules.
- 61 C. Timeline for Assistance Applications

62 Applications for assistance may be submitted throughout the year as funds remain available. Once
63 funding is no longer available, the LIMA program will cease accepting applications until additional funding
64 becomes available. If funding is not available at the time of application, the applicant may request that
65 the LIMA program hold the application (for up to 45 days) while the program awaits additional funding.
66 Unless otherwise indicated, the LIMA program will not hold applications for longer than 45 days while
67 waiting for funding.

68 If it has been longer than 45 days since the application was received by the LIMA program, the applicant
69 will be required to reapply and resubmit all necessary documentation.

70

71 **21.5 Criteria for selecting awards to homeowners**

- 72 A. The LIMA program shall receive and review applications and select applicants on a first-come,
73 first-served basis and will be evaluated based upon the following criteria:

- 74 1. The funds are available during the current state fiscal year/funding cycle to fund the radon
75 mitigation system and post mitigation testing at the time the application is received;
- 76 2. The radon test results indicate that radon levels in the livable areas of the home exceed the
77 EPA recommended radon action level of 4 picocuries per liter (4 pCi/l) for radon as tested by one
78 of the following accepted testing methods:
- 79 a. A short term radon test using a certified test kit;
- 80 b. A long term radon test using a certified test kit; or
- 81 c. A test or measurement performed by a certified radon measurement contractor;
- 82 3. The applicant has provided documentation that they own and occupy the home as their primary
83 residence;
- 84 4. The applicant meets the low income criteria in accordance with the most current U.S. Housing
85 and Urban Development (HUD) statewide income limits for Colorado as posted on the HUD
86 website.
- 87 B. The LIMA program shall have final authority to approve or deny the funding awards based upon
88 the documentation submitted or otherwise obtained by the department.

89 **21.6 Award limits**

- 90 A. Assistance amounts shall be limited to a maximum of \$2,500.00 per home/applicant unless
91 otherwise approved in advance by the LIMA program, and will be paid to the LIMA eligible
92 certified mitigation contractor.
- 93 B. A person may not apply for assistance more than one time in a calendar year.

94 **21.7 Awarding of assistance monies and appeal process**

- 95 A. The LIMA Program shall award funds and will specify the amount of the assistance based upon
96 the contractor's mitigation plan and the LIMA program statement of work requirements for LIMA
97 eligible certified mitigation contractors.
- 98 B. Any applicant who is denied funding or otherwise aggrieved in connection with the application
99 process may protest to the Radiation Program Manager or his/her designee.
- 100 1. Such protests must be submitted in writing within seven working days after such
101 aggrieved person knows, or should have known, of the facts giving rise thereto.
- 102 2. At the discretion of the Radiation Program Manager or his/her designee, protests may be
103 placed on the agenda of the Board of Health.
- 104 3. At the discretion of the Radiation Program Manager or his/her designee, funding may
105 proceed pending the final outcome of a Board decision regarding a protest/denial.
- 106 4. At the discretion of the Board, a protest may result in changes in the final selection of an
107 individual receiving an award, the amount of the award, and the termination of contracts
108 or other agreements that were awarded.

109

110 **21.8 Reporting requirements**

111 The LIMA program will develop and submit to the Board of Health an annual report no later than 60 days
112 after the end of the fiscal year which shall include:

113 A. The number of applications received, the number of applications denied, the total monies
114 expended and timeline for activities that were accomplished in the assistance year. Barriers to the
115 timely issuance of the funds will be documented as part of the annual report.

116 **21.9 Conflict of interest**

117 A. This section applies to any person:

118 1. Who reviews submitted applications; or

119 2. Who approves which applicants receive funding assistance and the amounts of
120 assistance.

121 B. Prohibited Behavior. No person may be involved in the activities specified in subsection A of this
122 section if that person has a conflict of interest, as that term is defined in section 21.1 herein.

123 C. Responsibilities of Persons with a Potential Conflict of Interest. A person who believes that he or
124 she may have a conflict of interest shall disclose the conflict as soon as he or she becomes
125 aware of it.

126 1. Any person shall disclose the conflict of interest in writing to the Radiation Program
127 Manager. If the Radiation Program Manager determines that the person has a conflict of
128 interest, the person shall recuse himself or herself from any of the activities specified in
129 paragraph 21.7.A relating to the conflict. The Radiation Program Manager shall assign an
130 alternate person to review any applications for which a conflict of interest may exist.

131

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BYLAWS

Radiation Advisory Committee

ARTICLE I: Name

The name of this organization shall be the Radiation Advisory Committee (“Committee” or “RAC”), created pursuant to the Colorado Radiation Control Act, 25-11-105, CRS, (“Act”) and operating within the Colorado Department of Public Health and the Environment (“Department”).

ARTICLE II: Purpose

The Act establishes the RAC under the Department. The focus of the Committee is to:

(a) Furnish to the Department such technical advice as may be desirable or required on matters relating to the Colorado Radiation Program (“Program”).

ARTICLE III: Powers and Duties

The Committee shall have the following powers and duties:

- (a) Review and provide input and viewpoints of a general nature on radiation issues, licensing, inspection, and registration activities conducted by the Program;
- (b) Provide input and technical advice to the Program on new and proposed amendments to existing radiation control regulations;
- (c) Propose new radiation rules and recommend potential rule **changes** to the Program;

ARTICLE IV: Members and Qualifications

Section 1. A member of the Committee shall be a resident of Colorado.

Section 2. The composition of the Committee shall reflect, to the extent practical, Colorado’s ethnic, racial, and geographic diversity.

Section 3. The Committee shall be established in accordance with CRS §25-11-105 and consist of nine (9) members appointed by the Governor as follows:

- (a) Three members representing healing arts;
- (b) Three members representing industry;
- (c) Three members representing higher education; and
- (d) No more than four (4) members from the same political party.

Section 4. Appointed members of the Committee shall serve for one **threefour (34)** year term; Members of the Committee may re-apply for up to one (1) additional term, provided that:

- (a) The current position is posted such that other qualified and interested parties have an opportunity to apply; or

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(b) Continued service of the current member is believed to be in the best interest of the Committee, the Radiation Program, and the Department; or

(c) No qualified or interested parties apply for a RAC position.

Members who serve one ~~threefour~~ (34) year term immediately followed (consecutively) by a ~~threefour~~ (34) year reappointment (a second term), may again re-apply for Committee appointment, provided that there is a minimum three (3) year lapse in time ~~between consecutive~~ following the second -terms.

Section 5. Any vacancy on the Committee shall be filled for the unexpired term in the same manner as the original appointment. Time spent on the Committee by individuals filling a vacancy left by a member who did not complete their term will not be counted towards any term limits.

Section 6. Members of the Committee shall serve without compensation; except that the members of the Committee may be reimbursed for necessary and actual expenses incurred in attendance at meetings or authorized business of the Committee.

Section 7. Regular attendance and participation is vital to the purpose of the Committee. Members accept the duty and obligation to attend meetings either in person or by teleconference and shall provide advance notice if they are unable to do so. Repeated, unexcused absences may be considered an abdication of the appointment and may be grounds for terminating a member's appointment at the recommendation of the Department or as specified in Section 9.

Section 8. Any member of the Committee may resign from the Committee at any time by notifying the Radiation Program Manager, or his/her designee, in writing. If a member finds it necessary to resign from the Committee, he/she is encouraged to assist the Department in nominating a suitable replacement and is encouraged to remain on the Committee until a suitable replacement has accepted his/her nomination.

Section 9. In accordance with CRS §25-11-105, Committee members serve at the discretion of the Governor. Any member of the Committee may be recommended for termination by a two-thirds majority vote of the entire Committee membership or at the discretion of the Radiation Program Manager, as a result of:

(a) Repeated, unexcused absences as discussed in Section 7;

(b) Violation of the Committee Bylaws;

(c) Failure to disclose a conflict of interest;

~~(d)~~ Ineligibility of membership, including no longer representing the category to which a member was appointed;

(e) Material misrepresentation or fraud in any statement to the Committee or to the public; or

(f) Conviction of a felony.

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To terminate the member's appointment, at least one member of the Committee shall submit his/her recommendation to the other members of the Committee, which shall approve or disapprove the recommendation by a two-thirds majority vote of the entire Committee membership. The Radiation Program Manager will approve of any recommendation for termination prior to final approval by the Governor.

Section 10. A notice shall be sent to the member, using the last address on file, setting forth the reason for the termination. Such notice shall be sent within fifteen days of the recommendation for termination. The Committee shall submit, in writing and within thirty days after sending the notice, a recommendation, a letter to the executive director of the department stating the Committee's recommendation for termination of membership. The member will be terminated by action of the Governor.

Section 11. In order to provide the Program and Department with the best technical advice, and in addition to the requirements of Sections 1 and 2 of this article, members shall meet one or more of the following minimum qualifications:

- (a) Hold a Bachelor's (or higher) degree in Health Physics, Engineering, or other scientific field or discipline and have three or more years experience in radiation safety matters where experience involved implementation of a radiation safety program at a medical, research, academic, or industrial facility; or
- (b) Be certified in Comprehensive Health Physics by the American Board of Health Physics; or
- (c) Be a physician, or medical physicist certified in a radiation related field (e.g., radiology, nuclear medicine, radiation oncology, medical physics, etc.) by a nationally recognized board; or
- (d) Hold an advanced degree in physics, medical physics, environmental health, or medicine, and have specialized knowledge in or have conducted research activities involving or related to radiation protection, epidemiology, and/or public health.

ARTICLE V: Officers

Section 1. The elected officers of the Committee shall be the Chair and Vice-chair. The Chair and vice-Chair shall be elected by majority vote of the entire Committee membership. The election shall be conducted annually **prior to or at** ~~during~~ the ~~first~~**second regular** meeting held after January 1 in each calendar year ~~in subsequent years~~. The Chair or Vice-Chair may be removed from office at any time for just cause as deemed sufficient by the Committee, by a two-thirds vote of the entire Committee membership. Written notice giving time, place, and purpose of this meeting shall be delivered to each member of the Committee at least ten (10) working days prior to the meeting. If the Chair or Vice-Chair is removed at such meeting, an election for a successor shall take place at the same meeting **when possible**.

Section 2. The term of office for the Chair and Vice-Chair shall be one year commencing at the close of the meeting at which they were elected. ~~For the period following initial adoption of these bylaws (2013),~~

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†The current Chair and Vice-Chair shall serve until the next election **or new Chair and Vice-Chair are chosen**, unless otherwise determined by the Committee.

Section 3. A vacancy in office shall exist in the event of the Chair's or Vice-Chair's resignation, removal from office, or death.

Section 4. Duties of the Chair shall be to:

- (a) Preside at all meetings of the Committee;
- (b) Develop meeting agendas with the advice and consent of the members and Program;
- (c) Observe and enforce the bylaws and policies of the Committee; and
- (d) Perform all such other duties of the office as provided by these Bylaws or prescribed by the Committee.

Section 5. In the absence of the Chair at any meeting in which a quorum is present, the Vice-Chair shall serve as Chair for that meeting only. Should the Chair and Vice-Chair both be absent at any meeting in which a quorum is present, the members present shall elect a **temporary** Chair to serve for that meeting only. A majority vote of the members present at the meeting shall determine **thesuch temporary** Chair ~~to serve for that meeting~~.

ARTICLE VI: Department Staff

Section 1. Committee activities shall be supported by Department staff or its designees.

Department staff may, among other things, provide background, present relevant information and make recommendations to the Committee.

ARTICLE VII: Meetings

Section 1. The Committee shall meet at least four (4) times per year, on a quarterly basis where possible, and more frequently as needed, at the call of the Chair, or by a majority vote of the entire Committee membership, or as requested or scheduled by the Program. Program staff will work with Committee members schedules to the extent possible.

Section 2. A quorum shall consist of five (5) members. A quorum shall be required for all formal actions **or recommendations** of the Committee.

- (a) Members may fully participate in a meeting via teleconference, or equivalent. For voting purposes, members attending the meeting via teleconference/telephone are considered to be equivalent to members physically present at the meeting location;
- (b) At the discretion of the Chair or by a vote of the majority of the Committee members present, issues may be voted upon via email or facsimile transmission provided responses are received within 48 hours of the vote request. At the discretion of the Chair, and with support of the Program, additional time

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may be allowed for voting on lengthy or **or other** technical documents **requiring additional consideration.**

(c) Any meeting may be cancelled by the Chair three working days prior to such meeting, when, in consultation with Program staff, the Chair determines the meeting is not needed, or when there will not be a quorum present.

Section 3. In the absence of a quorum, any business transacted is null and void, except to take measures to obtain a quorum or to reschedule another meeting or to make recommendations to the Chair as outlined in Section 5 below.

Section 4. All meetings of the Committee shall be open to the public in accordance with regulations of the Colorado Open Records Act and Sunshine Law. Notice of meetings shall be posted on the Program and/or Department website prior to the meeting.

Section 5. Except as otherwise specified in these bylaws, all formal decisions and recommendations from the Committee to the Department or Program shall have been approved by at least a quorum of members. If a quorum is not present during any given meeting, actions of the Committee – although non-binding - may be discussed by the members present, and a recommendation may be made to the Chair for further action, including a vote at a future time.

Section 6. No individual Committee member shall make a statement of proposal that purports to be that of the Committee unless the Committee has adopted such proposal. No member shall be prohibited from stating his or her personal opinions, provided they are clearly identified as such.

Section 7. Meeting minutes shall be kept for each RAC meeting held.

(a) Meeting minutes shall be reviewed and approved by a quorum of members following each meeting. Approval of minutes may be via electronic means (such as email), by telephone, teleconference, or by vote during a subsequent meeting;

(b) Meeting minutes shall be posted on the Department website upon approval by the RAC and as soon as practical following each meeting.

ARTICLE VIII: Subcommittees and Task Forces

Section 1. Formal subcommittees or ad hoc committees may be established as needed by majority vote of the Committee members present. Such subcommittees shall:

(a) Generally be conducted in an informal manner as circumstances permit;

(b) Be given stated purposes or areas of focus and recommended dates of discontinuance;

(c) Involve, as applicable or necessary, outside (non-RAC member) individuals, groups, organizations or associations.

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ARTICLE IX: Voting and Balloting Procedures

Section 1. In any instance in which a majority vote is called for:

- (a) The Chair may call for a show of hands, voice vote, standing vote, a secret/~~paper~~ ballot, or email vote, and such voting method shall determine the result of the vote, except,
- (b) In the case of election of the Chair and Vice-Chair, the vote shall always be ~~by secret ballot~~ as outlined in Section 2 and 3 of this Article, unless a majority of the entire Committee membership determines otherwise as described in Section 1 of this Article.
- (c) No proxy or absentee voting shall be allowed.

Section 2. ~~Voting Ballots~~ shall be ~~by paper ballot~~~~pieces of paper~~, by show of hands, or ~~ballots~~ which may be submitted by e-mail, or as designated by the Chair.

Section 3. If no candidate or issue receives a qualifying vote, another ballot shall be taken. If further ballots need to be cast to determine a single winner, it shall be between the two candidates or issues receiving the highest number of votes on the immediate preceding ballot.

Section 4. All members, including the Chair ~~and Vice-Chair~~, shall have voting rights.

ARTICLE X: Parliamentary Authority

Section 1. Meetings shall be conducted ~~generally~~ in ~~general~~ keeping with Robert's Rules of Order, but shall be as informal as circumstances permit.

ARTICLE XI: Adoption of Bylaws

Section 1. These Bylaws shall take effect immediately upon a two-thirds majority vote of the entire Committee membership.

ARTICLE XII: Amendment of Bylaws

Section 1. The Bylaws may be amended in whole or in part at a meeting of the Committee by a two-thirds majority vote of the entire Committee membership provided that such amendment was submitted to the Committee at least ten (10) working days prior to the meeting or voting date at which such amendment is to be offered and remitted to all members of the Committee.

Section 2. Adopted amendments shall take effect immediately upon adoption.

ARTICLE XIII: Conflict of Interest

Section 1. Article 18 of Title 24 of the Colorado Revised Statutes sets forth Standards of Conduct for government employees, public officials, members of the general assembly, and members of boards and Board of Health. With respect to members of boards and Board of Health, such members "shall not perform an official act which may have a direct economic benefit on a business or other undertaking in

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which such member has a direct and substantial financial interest”, CRS. § 24-18-108.5(2). A conflict of interest means a situation in which a person has a duty to more than one person or organization, but cannot do justice to the actual or potentially adverse interests of both parties. This includes when an individual's personal interests or concerns are in conflict with the best interests of a customer, or when a Committee member's personal interests are contrary to his/her charge as a Committee member to conduct Committee business. A conflict does not exist merely because a Committee member, a Committee member's employer or a Committee member's client has a pre-established policy position or self-interest regarding an issue being considered by the Committee, or when a Committee member or member's organization is regulated by the Program.

(a) Factors to Consider When Reviewing a Potential Conflict of Interest as a Committee member. In deciding whether there is a conflict of interest, the Committee or a Committee member shall consider the definition of a conflict of interest and other relevant information, including:

- (i) The General Assembly's intent and decision to appoint a Committee comprised of individuals with expertise and involvement with radiation matters for the benefit of the State of Colorado;
- (ii) The disclosure of potential conflicts of interest by the Committee member upon nominating him/herself to the Committee; and
- (iii) Whether the potential conflict of interest impedes the Committee's independence of judgment.

(b) Participation in Committee Grant Programs By Members

- (i) It is the express intent of the Committee to prevent the exclusion of any member, a member's employer, or a member's client from participating in grant programs administered by the Committee. Specifically, members will be provided equal opportunity to compete in selection processes for receiving grant funds for any eligible projects, and to be fairly awarded funding based on the merits of their proposals.
- (ii) Members shall not participate in the review or ranking of any grant proposal or in any oversight or administration of any subsequent grant award when it is determined that an actual conflict of interest exists according to procedures in Article XIII, Section 1 (c) of this document.

(c) Disclosure of Actual or Potential Conflict of Interest.

- (i) A Committee member shall take one of the following steps if she or he perceives that a conflict of interest exists or may exist:
 - A. Disclose the basis of the potential conflict of interest to the Committee and others in attendance before the discussion begins, or as soon thereafter as the conflict of interest is perceived, and disqualify him/herself from any further participation or voting on the matter at hand; or
 - B. Disclose the basis of the potential conflict of interest to the Committee and others in attendance before the discussion begins, or as soon thereafter as the conflict of interest is perceived: then, if the Committee member does not disqualify him/herself from further participation in the matter, the Chair will ask for comments from any other Committee member, parties to the matter before the Committee, or any member of the public present. Except for the member disclosing the potential conflict of interest, the

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Committee shall vote on whether a conflict of interest exists and the Committee member disclosing the potential conflict shall be bound by the Committee's vote. If a conflict is found to exist, the Committee member disclosing the conflict shall be disqualified from further participation or voting on the matter at hand. As described above, members whose grant applications are pending for review by the Committee shall be disqualified by the Committee from participating in the discussion and review of such grant.

ii.) A conflict of interest may also be raised by other Committee members, the parties to the matter before the Committee, and/or any member of the public. In such instances, the Committee member may either choose to recuse him/herself from further participation in the matter, or the Committee may vote on disqualification of the member as described in section (c)(i)(B) above.

iii.) Committee meeting minutes shall reflect all disclosures of actual or potential conflicts of interests, and shall record the findings of the Committee or the member concerning disqualification.

Amendments to the August 15, 2013 Bylaws of the Radiation Advisory Committee were approved by a hand vote during the August 15 TBD, 2013 16 regular meeting. A total of 8 members voted thereby meeting the criteria of Article XI herein, with 7 members voting in favor of the bylaws, and 1 member opposed to the bylaws. One member was absent from the meeting.