

Integrated Science Support, Inc 14450 N 169 Hwy, Suite O Smithville, MO 64089 (816) 390-9011

MQSA Physicist Qualifications Stephen E. Hale Jr., Ph.D.

Contents

FDA Mammography Physicist Qualification Certificate

Missouri Qualified Expert Certificate

KS Medical Physicist Certificate

IA Mammography Physicist Certificate

Missouri Mammography Physicist Initial Qualifications Certificate

Initial Training for Film-Screen/Digital/Tomosynthesis Mammography

Continuing Education

Continuing Experience

Note: The Missouri Initial Qualifications Certificate does NOT have an expiration date.

Distributed March 2023



Public Health Service

Food and Drug Administration 10993 New Hampshire Avenue Silver Spring, MD 20993

September 13, 2012

Stephen E. Hale, Ph.D. Integrated Science Support, Inc. 2027 N. 36th Street St. Joseph, MO 64506

Dear Dr. Hale:

After reviewing your credentials, the Division has determined that you meet the initial qualification requirements described in Section 900.12(a)(3)(i) of the final regulations which went into effect on April 28, 1999. A copy of this letter may be provided to your facility as documentation that these requirements are met. For MQSA documentation purposes, you will also need to supply all facilities where you provide mammography services a copy of your current State approval, State license, or Board certification. Please be aware that if your State approval or State license expires after a certain period, you must provide to your facilities a new copy of the documentation after each renewal. Failure to provide your facility with proper valid documentation may lead to a citation.

From the information you provided for our review, your starting date for meeting your continuing education and continuing experience requirement is July 16, 2010. If you have any further questions regarding this matter, please contact the MQSA Hotline at 1-800-838-7715.

Sincerely yours,

Heley Barr, Mis

Helen J. Barr, M.D., Director Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs Center for Devices and Radiological Health

The Individual Below Is Hereby Recognized by the Missouri Department of Health and Senior Services, Bureau of Diagnostic Services as a

Qualified Expert in Radiation Safety Stephen Hale, Jr. Ph.D.



Recognition of Qualified Expert Status Valid

<u>10/24/2022</u> Until: <u>10/24/2024</u> Qualified Expert ID:

QE033

John Jargstu



Administrator, Bureau of Diagnostic Services



- ✓ Health Physics Consultation
- Radiation Shielding Design
- Diagnostic Radiographic (Medical/Chiropractic/Podiatric)
- Fluoroscopy/Inverventional Radiology
- ✓ Non-Medical/Industrial/Academic/Research
- □ Therapy/Linear Accelerator

 Mammography *(FDA MQSA Standards)
*MRCP has determined that this Qualified Expert currently meets FDA's MQSA standards for approval as a mammography medical physicist, and a copy of his/her current qualifications is maintained by the MRCP.

Per requirements in 19 CSR 20-10.010, this person is found to have the necessary training and experience to be able to perform dependable radiation surveys. Despite recognition of this person's status as a Qualified Expert, the Department makes no warranty either expressed or implied as to the quality of specific services provided to an individual facility. Complaints regarding this person's ability to continue to conduct dependable radiation surveys may be directed to the Radiation Control Program at 573-751-6083 or MRCP@health.mo.gov

Other :



KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

Bureau of Community Health Systems Radiation Control Section 1000 SW Jackson, Ste. 330 Topeka, KS 66612-1365



Kansas X-ray Service Provider Registration

Stephen E. Hale, Jr., Ph.D.

Is hereby registered as a provider of radiation services in the specialty areas specified below in accordance with Article 35 of the Kansas Radiation Protection Regulations.

SERVICE PROVIDER NUMBER

SERVICE PROVIDER SPECIALTY

REGISTRATION DATE

KS-113

Medical Diagnostic X-ray Physicists

July 26, 2016

FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT By Jason Barney, RRPT



Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director

March 14, 2023

Stephen Hale 14450 N 169 HIGHWAY SUITE O SMITHVILLE, MO 64089

Dear Stephen Hale,

This letter is to verify that you have met all MQSA initial qualification requirements as stated in the final regulations, 900.12(a)(3)(i) and all Iowa registration requirements for a medical physicist in: Mammography: Digital Mammography: Film Screen Mammography: Tomosynthesis

Therefore, you are permitted to perform all those procedures required under Iowa Radiation Machines Rules for the above categories. Your **registration number MPHY10027** expires on April 30, 2024.

Each Iowa facility where you provide medical physics services must have a copy of this Medical Physics Approval letter.

Thank you for your cooperation. Please call 515-285-3246 if you have any questions.

Sincerely,

Patty Risberg

Patty Riesberg, Bureau Chief Bureau of Radiological Health Office Phone: (515) 281-0405 Fax: <FaxNumber> Email: Patricia.Riesberg@idph.iowa.gov



Missouri Department of Health and Senior Services P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010 RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466 Margaret T. Donnelly



Jeremiah W. (Jay) Nixon Governor

July 16, 2010

Qualifications Review of Individuals Providing Medical Physics Support Services in Mammography

Missouri Rule 19 CSR 20-11.060 authorizes the Missouri Department of Health and Senior Services (DHSS) to approve individuals providing medical physics support to suppliers of mammography services. DHSS's Missouri Radiation Control Program (MRCP) has reviewed documentation for:

Name:	Stephen E. Hale, Jr. Ph.D.	
Company or Title:	Integrated Science Support	
Address:	1802 Union St.	
City/State/Zip Code:	St. Joseph MO 64501	

Director

Review of Initial Oualifications

Initial Requirement	Documentation Required by FDA	Documents Reviewed/On File at MRCP	
License,	State License,	Missouri Dept. of Health & Senior Services	
Approval or	State Approval Letter or	State Approval Letter	
Board Certified	ABR/AOBR Certificate in Diagnostic Physics	July 16, 2010	
Qualifying	ualifying Degree in Physical Science: Ph.D. in Physics		
Degree	PhD or MS with 20 hours in Physics	University of North Carolina at Chapel Hill	
		May 16, 1999	
Specialized	PhD or MS Degree: 20 contact hours	Letter from Jon J. Erickson, Ph.D. documenting	
Survey Training*		Dr. Hale completed 20 contact hours of training	
		in surveying mammography facilities.	
		July 6, 2010	
Initial	PhD or MS Degree: 1 facility and 10 units	Letter from Jon J. Erickson, Ph.D. documenting	
Experience*		Dr. Hale surveyed, under direct supervision,	
		one (1) facility and ten (10) mammography units.	
		July 6, 2010	
New Modality	Certificate(s) documenting 8 hours modality-specific	Letter from Jon J. Erickson, Ph.D. documenting	
Training	training prior to surveying in that modality	Dr. Hale received eight (8) hours of training in	
(if applicable)		surveying digital mammography units.	
		July 6, 2010	

*Individual may attest to fulfilling this requirement if training and/or experience obtained prior to October 1, 1994.

MISSOURI APPROVAL IS GRANTED

Start Date: July 16, 2010

Documentation of your continuing education and experience was reviewed and found to be acceptable. Remember that documentation of continuing education and experience must be kept on file at all facilities where you provide medical physics services. Inform MRCP of any changes in name, address or telephone number. Please note FDA has decreed this review/approval is not reciprocal between states. You will need a similar review by each state in which you provide these services. You can also send your documentation directly to FDA for their review.

If you have any questions or need additional information, please contact the Missouri Radiation Control Program at (573) 751-6083.

Review performed by: Charles C. Arnold FDA Certified MQSA Inspector #I2227 Missouri Radiation Control Program Bureau of Health Services Regulation

www.dhss.mo.gov

Healthy Missourians for life.

The Missouri Department of Health and Senior Services will be the leader in promoting, protecting and partnering for health.

AN FOLIAL OPPORTUNITY / AFFIRMATIVE ACTION FMPI OYER: Services provided on a nondiscriminatory basis



Integrated Science Support, Inc

1802 Union St, Joseph, MO 64501 (816) 390-9011 (800) 306-4477 FAX (816) 390 – 8003

July 13, 2010

To: Whom It May Concern

From: Jon J. Erickson, Ph.D., DABR

Subject: Initial MQSA Training Requirements for Stephen. E. Hale, Jr., Ph.D.

This memo is to certify that between the dates of April 20, 2010 and July 6, 2010, Stephen. E. Hale, Jr, Ph.D. received 20 contact hours of training in the surveying of mammography x-ray systems.

This memo is also to certify that during the same period of time he performed 10 mammography system inspections under the direct supervision of Jon J. Erickson, Ph.D, DABR.

This memo is also to certify that during the same period of time he received 8 hours of training in surveying digital mammography units. This training was conducted by Jon J Erickson, PhD, DABR

The records of this training and experience are available in the corporate offices of Integrated Science Support, Inc. at 1802 Union, Saint Joseph, MO 64501.





The Women's Health Company

Hereby awards this Certificate of Completion to

Stephen E. Hale Jr., Ph.D.

For completing 3 hours of **HOLOGIC's** Online Tomosynthesis Training For Medical Physicists in accordance with MOSA guidance for Digital 3-D Mammography Systems*

Selenia[®] Dimensions[®] Quality Control and Set-up Procedures

On this Date: Feburary 8, 2012

Authorized by: ______ Leorga K. Kitzke

VP, Product and Clinical Education, Breast Health

* MQSA guidelines require each Medical Physicist to complete eight hours of product training prior to using the Selenia DimensionsTM for clinical use.

HOLOGIO The Women's Health Company

Hereby awards this Certificate of Completion to

Stephen E. Hale Jr., Ph.D

training in accordance with MQSA guidance for Digital 3-D Mammography Systems* For completing 2 hours of HOLOGIC's product

Selenia DimensionsTM Quality Control and Set-up Procedures

On this Date: 11/15/2012

Fodd Vincent BMI Authorized Instructor:

* MQSA guidelines require each Medical Physicist to complete eight hours of product training prior to using the Selenia DimensionsTM for clinical use.



. . .

Hereby awards this Certificate of Completion to

Stephen E. Hale Jr., Ph.D

training in accordance with MQSA guidance for Digital 3-D Mammography Systems* For completing 4 hours of HOLOGIC's product

Selenia DimensionsTM Quality Control and Set-up Procedures

On this Date: 11/14/2012

odd Vincent BM Authorized Instructor:

* MOSA guidelines require each Medical Physicist to complete eight hours of product training prior to using the Selenia DimensionsTM for clinical use.

Certificate of Completion Stephen Hale Jr., PhD, DABR

In recognition of successful completion of the GE Healthcare Digital Breast Tomosynthesis Supplemental Training Program



Jessie Jacob, MD, MMM GE Chief Medical Officer, Women's Health April 29, 2015

<u>GE Healthcare</u>



November 24, 2015

To: Whom it may Concern From: Jon Erickson, Ph.D., DABR Subject: Physicist training for General Electric

This is to certify that Stephen E. Hale Jr., Ph.D., DABR, has received 8 hours of in-service training in the unique aspects of the General Electric Seno-Clair Breast Tomosynthesis system.

CERTIFICATE of **COMPLETION**

This is to certify that:

Stephen Hale

successfully completed

MAMMOMAT Inspiration Tomosynthesis for Medical Physicists This 3.0 hour web based training on Siemens Tomosynthesis for Digital 3-D Mammography Systems. Training includes Siemens unique feature training.

> Course ID: 90010613 Completion Date: 09/10/2015

Credits Type/Earned: 3 Category A

Approving Organization: AHRA

Reference Number: END1784

Approved Date Range: 08/13/2015 - 08/31/2016

Gregory Scrensen, MD President & CEO



CERTIFICATE of COMPLETION

This is to certify on (date): 9 (8 15

Stopha E. Hale Jr.

has successfully completed a total of 5.0 hours of Siemens hands-on Tomosynthesis with MQSA guidelines for Digital 3-D Mammography Systems: training for Medical Physicists in accordance

Marie With

Nanci L. Wozniak, BS, RT(N), CNMT Vice President, Education Services

medical

SIEMENS

CAMPEP

Commission on Accreditation of Medical Physics Education Programs, Inc. Certificate of Medical Physics Continuing Education Credits ----Transcript----

Stephen Hale Jr.

14450 N. 169 Hwy Suite O Smithville, MO 64089 US

Participated in the following CAMPEP accredited educational program(s) and is awarded Medical Physics Continuing Education Credits (MPCECs) as designated

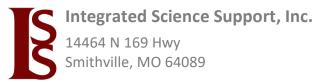
Program Title	Date Credits Earned	Category/SubCategory	EA Title	Credits	
2021 AAPM Online Continuing Education	10/13/2021	Diagnostic Radiology: Mammography	An Overview of the New ACR DBT QC Tests and Phantom 2019	1	
2021 AAPM Online Continuing Education		Diagnostic Radiology: Mammography	BICOE Accreditation of Stereotactic Breast Biopsy and Breast Ultrasound Systems	1	
2021 AAPM Online Continuing Education		Diagnostic Radiology: Mammography	DMIST Quality Control Part II	1	
2021 AAPM Online Continuing Education 10/13/2021 Diagnostic Radiology: Mammography Effect of Calcification on Image Q		Effect of Calcification on Image Quality	1		
2021 AAPM Online Continuing Education	e Diagnostic Radiology: Emerging Clinical Digital Mammography Technologies		1		
2021 AAPM Online Continuing Education 07/10/2021		Diagnostic Radiology: Mammography	Evaluating the Performance of Stereotactic Breast Imaging Biopsy Systems 2019	1	
2021 AAPM Online Continuing Education	Online Diagnostic Radiology: Force balancing in mamme Continuing Diagnostic Radiology: Force balancing in mamme		Force balancing in mammographic compression	1	
2021 AAPM Online Continuing Education	line ntinuing 07/08/2021 Diagnostic Radiology: Multi-Modality Stereotactic Breast Biopsy Systems		1		
2021 AAPM Online Continuing Education	ine Diagnostic Radiology: and GE SenoClaire Digital Breast Tomosynthesis Units			1	
2021 AAPM Online Continuing Education	ne inuing 10/18/2021 Diagnostic Radiology: Robust measurement of the slice-sensitivity Mammography profile in breast tomosynthesis		1		

2021 AAPM Online Continuing Education	07/08/2021	Diagnostic Radiology: Mammography	Stereotactic Breast Biopsy: Historical reminder	
2021 AAPM Online Continuing Education	10/13/2021	Diagnostic Radiology: Mammography	The New ACR Mammography QC Manual 2019-An Overview and Early Adopter Perspectives	1
2022 AAPM Online Learning Center	03/31/2022	Diagnostic Radiology: Mammography	2305-N Development of realistic physical breast phantoms matched to virtual breast phantoms based on human subject data	1
2022 AAPM Online Learning Center	02/17/2022	Diagnostic Radiology: Mammography	ology: 4258-N Digital Breast Tomosynthesis Unique Features of the GE SenoClaire Tomosynthesis System	
2022 AAPM Online Learning Center	03/30/2022	Diagnostic Radiology: Mammography	4263-N The impact on lesion detection via a multi-vendor study: A phantom-based comparison of digital mammography, digital breast tomosynthesis, and synthetic mammography	1
2023 AAPM Online Learning Center	01/12/2023	Diagnostic Radiology: Mammography	1898-N Breast Cancer Screening and Digital Mammography	1
2023 AAPM Online Learning Center	01/12/2023	Diagnostic Radiology: Mammography	4417-N From Detection to Prediction: Imaging Markers of Breast Cancer Risk	1
Total Released Credits:			17	

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The following is a true representation of the Continuing Mammography System Evaluation Experience for the indicated Physicist.

The F. Alleh 1/18/2023

Stephen E. Hale, Ph.D., DABR President Date

Continuing Experience Summary for Stephen E. Hale, Ph.D.

Facility State	MQSA Number	System Model	Date Performed
IA	10408338	Dimensions	5/5/2021
IA	129296	Essential	6/30/2021
KS	225809	Selenia Dimensions	1/27/2021
KS	212076	Selenia Dimensions	2/25/2021
KS	118612	Selenia Dimensions	2/26/2021
KS	109652	Senographe Pristina	3/18/2021
KS	223065	SenoClaire	8/5/2021
KS	246931	Selenia Dimensions	4/13/2022
KS	109652	Senographe Pristina	4/14/2022
KS	243046	Selenia Dimensions	5/23/2022
KS		Selenia Dimensions	9/23/2022
MO	116079	Dimensions	1/29/2021
MO	226174	Essential w/ MTD	2/12/2021
MO	116079	Dimensions	3/19/2021
MO	231960	Pristina	5/6/2021
MO	116079	Selenia Dimensions	8/27/2021
MO	200824	Selenia Dimensions	9/23/2021
MO	209619	Essential w/ MTD	11/23/2021
MO	187526	Selenia Dimensions	12/22/2021
MO	116079	Dimensions	1/21/2022
MO	226174	Essential w/ MTD	3/3/2022
MO	183335	Selenia Dimensions	8/3/2022

Facility State	MQSA Number		System Model	Date Performed
MO	116079		Selenia Dimensions	8/12/2022
MO	200824		Selenia Dimensions	9/6/2022
MO	187526		Selenia Dimensions	11/21/2022
MO	209619		Essential w/ MTD	12/2/2022
MO	116079		Dimensions	1/6/2023
IA Facilities:	2	IA Machines:	2	
KS Facilities:	7	KS Machines:	9	
MO Facilities:	8	MO Machines:	16	