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 January 2024



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,

Helen J. Barr, M.D., Director

When Barr, MA

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



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)
- ✓ CT
- **☑** Bone Density/DEXA
- ✓ Dental (Non-CBCT)
- ✓ Veterinary Radiology
- \square Other :

*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



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

Jason Barney, RRPT



Protecting and Improving the Health of Iowans

Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director

April 12, 2022

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, 2023.

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,

Angela Leek, Bureau Chief Bureau of Radiological Health Office Phone: 515-281-3478

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Fax: 515-281-4529

Email: angela.leek@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



Jeremiah W. (Jay) Nixon Governor

Margaret T. Donnelly
Director

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

Review of Initial Qualifications

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	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

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.





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 MQSA guidance for Digital 3-D Mammography Systems*

Selenia® Dimensions® Quality Control and Set-up Procedures

On this Date: Feburary 8, 2012

Authorized by: Lenga M. Klitzke

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.

TOIDOUT

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

Authorized Instructor:

Todd Vincent BMI

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

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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 4 hours of HOLOGIC's product

Selenia DimensionsTM Quality Control and Set-up Procedures

On this Date: 11/14/2012

Authorized Instructor: Jose

* MQSA guidelines require each Medical Physicist to complete eight hours of product training prior to using the Selenia Dimensions TM 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**



GE Healthcare

Integrated Science Support, Inc 2027 N. 36th St. St, Joseph, MO 64506

2027 N. 36th St. St, Joseph, MO 64506 (816) 390-9011 (800) 306-4477 Fax (816) 390-8003

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

SIEMENS

Gregory Scrensen, MD President & CEO

CERTIFICATE of COMPLETION

This is to certify on (date):_

Stepha E. Hale Ir.

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

Navi Wife

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

medical

Logged in as shale@issphysics.com, CAMPEPID# 28367 | Logout

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	<u>Category/SubCategory</u>	<u>EA Title</u>	<u>Credits</u>
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	4258-N Digital Breast Tomosynthesis Unique Features of the GE SenoClaire Tomosynthesis System	1
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	01/17/2023	Diagnostic Radiology: Mammography	1802-N Acquisition Parameter Selection in Digital 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
2024 AAPM Online Learning Center	01/16/2024	Diagnostic Radiology: Mammography	1632-N Manufacturers Quality Control Output Templates	1
2024 AAPM Online Learning Center	01/21/2024	Diagnostic Radiology: Mammography	2263-N ACR Accreditation of Stereotactic Breast Biopsy Systems and of Breast Ultrasoud Systems 2015	1
2024 AAPM Online Learning Center	01/16/2024	Diagnostic Radiology: Mammography	2484-N Mammography 1 Contrast Enhanced Spectral Mammography	1
2024 AAPM Online Learning Center	01/19/2024	Diagnostic Radiology: Mammography	4164-N Unique Features of the Siemens Inspiration Digital Breast Tomosynthesis System	1

1 of 2 1/22/2024, 12:38 PM

2024 AAPM Online Learning Center	01/19/2024	Diagnostic Radiology: Mammography	4256-N Digital Breast Tomosynthesis Physics: Basics to Advanced	1
2024 AAPM Online Learning Center	01/21/2024	Diagnostic Radiology: Mammography	4260-N Changing Perceptions and Updated Methods for Mammography	1
2024 AAPM Online Learning Center	01/15/2024	Diagnostic Radiology: Mammography	4326-N Updates on the New ACR FFDM Manual	1
2024 AAPM Online Learning Center	01/19/2024	Diagnostic Radiology: Mammography	4535-N Design and initial evaluation of a novel physical breast phantom to monitor image quality in digital breast tomosynthesis	1
2024 AAPM Online Learning Center	01/15/2024	Diagnostic Radiology: Mammography	N-4575 Evaluating the Performance of Stereotactic Breast Imaging Biopsy Systems	1
Total Released Credits:			15	

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2 of 2



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

1/11/2024

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

Ty F. 9Wh

Date

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

	-8	,	
Facility State	MQSA Number	System Model	Date Performed
IA	243021	Selenia	2/13/2023
IA	10408338	Dimensions	5/23/2023
IA	129296	Essential	6/14/2023
KS	246931	Selenia Dimensions	4/13/2022
KS	109652	Senographe Pristina	4/14/2022
KS	243046	Selenia Dimensions	5/23/2022
KS	171611	Selenia Dimensions	9/23/2022
KS	246931	Selenia Dimensions	4/24/2023
KS	243046	Selenia Dimensions	5/26/2023
MO	116079	Dimensions	1/21/2022
MO	226174	Essential w/ MTD	3/3/2022
MO	183335	Selenia Dimensions	8/3/2022
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
MO	238396	Selenia	2/1/2023
MO	167411	Dimensions	2/6/2023
MO	209619	Pristina	2/8/2023
MO	226174	Essential w/ MTD	2/20/2023
MO	116079	Dimensions	3/3/2023

Facility State	MQSA Number	System Model	Date Performed
MO	139709	Selenia Dimensions	5/24/2023
MO	139709	Selenia Dimensions	5/24/2023
MO	116079	Selenia Dimensions	8/11/2023
MO	200824	Selenia Dimensions	9/26/2023
MO	187526	Selenia Dimensions	11/14/2023
IA Facilities:	3 IA Ma	chines: 3	
KS Facilities:	4 KS Ma	chines: 6	
MO Facilities:	9 MO N	achines: 18	