



J Wise S. Miyazaki Z. Chen S. Erhardt

2015 ANNUAL REPORT

A. Mission and Goals of the North Central Region IR-4 Program

<u>The mission</u> of the NC Region IR-4 program is to ensure that safe and effective pest management tools are available for growers of specialty crops, including ornamental crops, and for minor uses on major crops through the generation of high quality field and laboratory data.

<u>The goals of the program</u> are to identify pest management needs for these crops in the region, to participate in the prioritization of these needs at the national level, to conduct field research and analytical studies that develop the information to obtain clearances and label additions from USEPA to meet these needs, and, finally, to make information available on the status and progress of these studies and their final outcome to growers and other interested parties.

B. Background and Justification

The IR-4 Minor/Specialty Crop Pest Management Project (IR-4 Project) is a comprehensive, national program that consists of six units working together on a common mission to meet the nationally defined goals and objectives presented above. The national program is currently comprised of: IR-4 National Headquarters (IR-4 HQ), four Regional IR-4 Centers (Northeast, North Central, Southern and Western), and the USDA Agricultural Research Service (USDA-ARS) Office of Minor Uses. The North Central Region (NCR) program is responsible for the operations of the program in the 12 states of the region (IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD and WI) and has been located at Michigan State University (MSU) since the inception of the regional programs in 1967. The NCR program, while located at MSU, has developed three field research centers in Michigan and Wisconsin, and works with other field research cooperators around the region, has established an advanced laboratory unit at MSU, and, in response to the Good Laboratory Practice (GLP) requirements of EPA, has developed a group of Quality Assurance personnel to serve the region. The NC program also works co-operatively with the USDA-ARS IR-4 field research unit located at Wooster, OH. Each of the 12 states of the Region (with the current exception of Missouri) has one or more State Liaison Representatives who identify research needs in their state and transmit back the activities of the program to interested parties within their state.

In the NCR program, needs are identified and prioritized by research and extension personnel, farmers, grower organizations and others at a regional meeting, and prioritized at a National Food Use Workshop. Field trials in which pest management chemicals are applied to food crops are conducted and crop samples are collected and analyzed for the magnitude of residues. All food use research is conducted under the requirements for Good Laboratory Practice issued by the USEPA. The analytical reports, after Quality Assurance checks, are forwarded to USEPA as petitions for the development of clearances for these

materials. Efficacy (performance) studies on key pests that are currently difficult to control are also funded where this is deemed necessary to obtain later clearances for these pests. Like food uses, ornamental projects are prioritized at a specific workshop and assigned to collaborators in the NCR. The ornamentals projects focus on efficacy and crop safety (phytotoxicity) with primary emphasis on pests for which no satisfactory controls currently exist. The reports are sent to the registrants of the chemicals to assist in obtaining label amendments to include new crops and pests. Projects to conduct research and efficacy demonstrations with biopesticides are also solicited and prioritized nationally at the annual Biopesticide Workshop.

The plant protection industry has limited economic incentive to conduct the research necessary to obtain registrations for most specialty crops. To fill this pest management gap, IR-4 develops the data that provide legal, effective, safe and IPM-compatible pest control agents. Without this program, many specialty crops could no longer be produced in the USA with severe economic implications for American agriculture, food processors, and consumers. Specialty crop growers and food processors are the primary beneficiary of the IR-4 Project by having legal access to effective pest management products, but the general public also benefits by having a safe, healthy, and reasonably priced food supply.

C. Budget

Funding for the NCR IR-4 program comes primarily from USDA/NIFA as an annual competitive research grant. We received \$1,916,099.00 for FY15. This is a decrease of \$41,407 compared to FY14. The starting date for the FY15 funding was August 15th.

D. Overview of Productivity in 2015

This was a productive year for the IR-4 North Central Region. Field Research Directors (FRD) effectively worked around weather-related events, such as frosts and flooding, to carry out field trials to completion. The NC lab has worked hard to overcome backlogs associated with unexpected problems and difficult studies. A total of 112 food use reports were submitted for the region. In the ornamentals program, a total of 70 studies of pesticide efficacy and crop safety were submitted from the region. A downward trend of trial completions is in part reflective of fewer project assignments for NCR, however the costs of completion continue to rise for the field and lab because of expanding demands and greater analytical complexity of test substances. There were five EPA compliance inspections conducted in the NC Region in 2015, and all were closed without adverse findings. This illustrates the continuing effectiveness of our region's FRDs, Laboratory and Quality Assurance personnel. More details of these results are provided below.

E. Future Challenges

The IR-4 program faces several challenges in the coming year. Based on projections from the US Congress Agriculture committee, we are anticipating relatively flat funding for this next year's NIFA grant proposals. This will add continued pressures on the NC Region for maintaining our facilities, field and lab personnel, while providing the highest possible outputs to the specialty crop growers of the region. In addition, the IR-4 Project Management Committee is investigating a shift from the current NIFA competitive grant to a USDA Cooperative Agreement funding line as a way to address the real costs of conducting this work on university campuses. If successful, this avenue would provide IR-4 with a four year grant and 10% IDC (indirect cost).

While pesticide discovery in the private sector appears to be in a downward cycle, the overall cost of conducting residue trials, start to finish, are increasing. Additionally, the deadlines for completing residue studies have become shorter and much more critical. EPA now insists that all tolerance requests for a given pesticide must be bundled together for consideration rather than submitted piecemeal as in the past. Also, agrichemical companies are increasingly reluctant to submit petitions to EPA more often than necessary since these can trigger new and expensive data requirements by EPA. The result is that a greater

proportion of IR-4 resources are needed for coordination roles between IR-4 HQ and regional labs, registrants and EPA.

International collaboration efforts appear to be a new and promising opportunity for IR-4. The very effective collaboration with the Canadian IR-4 program has been recognized for some time now, recognized by the invitation to participate in the joint US-Canadian Regulatory Cooperation Council (RCC). IR-4 is also taking a leading role in encouraging global harmonization and more efficient data use at the international level including the sponsorship of First Global Minor Use Priority Setting Workshop in Chicago on September 20-22, 2015. IR-4 has also successfully received FAO funding to lead in Capacity Building efforts in SE Asia, South America, Africa and Egypt, with hopes for harmonizing Maximum Residue Limits (MRLs) and in turn enhance global trade opportunities of US Specialty Crop producers.

F. Personnel Changes/Additions in 2015

John Wise, Entomology, MSU became Director of IR-4 North Central Region effective July 1, 2014. Bob Hollingworth, Director Emeritus, remained as Associate Director until July 2015. As a result, Anthony VanWoerkom, Entomology, MSU is a new FRD in the NC region. Dave Williams, IL state liaison also retired.

Ms. Eileen Nelson replaced Dr. Bryan Jensen as the new QAO for the IR4 Wisconsin Research Center in later season in 2015. Eileen completed the GLP/QA training and the eQA system training conducted by Dr. Zhongxiao Michael Chen in the summer. So far she completed one critical in-life inspection in December 2015 and that was a good start.

We thank Bob, Dave and Brian for their dedicated contributions to the IR-4 Project for many decades.

G. Regional IR-4 Activities:

Field Research

Food Uses: As a result of the 2015 NC Regional IR-4 Advisory Committee Meeting in East Lansing, MI, the subsequent IR-4 Food Use Workshop, and the National Research Planning Meeting, 70 food use field studies (58 GLP residue trials and 12 Efficacy/Crop safety studies) were assigned in 2015 while 76 field studies (68 GLP and 8 Efficacy/Crop safety) were conducted in 2014 (down 8%). From 1/1/2015 through 12/31/2015 the region completed and sent to IR-4 HQ field data packages for 110 food use field trials (99 GLP trials and 11 Efficacy/Crop safety trials). See Table 4 of this report for the distribution and status of funded 2015 field research projects as of December 31, 2015. The 2015 projects were completed by the end of the 2015 first quarter. Fig. 1 provides a graph of all projects completed for the 2005-2015 period as a 3-year moving average (food, ornamentals and lab) as of December 31, 2015.

Ornamental Horticulture: Significant changes have been made nationally in the IR-4 Ornamental Horticulture program that brings with it an enhanced focus on efficacy research based on key pests and needs (as determined at the Ornamentals Workshop). In the ornamentals program in 2015, 61 studies of pesticide efficacy and crop safety were completed and the reports were forwarded to IR-4 HQ. The following scientists (Table 1) participated in the program.

PROJECT	STATE	COOPERATOR
In Season Crop Safety	IA	Diana Cochran
		Iowa State University
Ornamental Grass Crop Safety	IA	Diana Cochran
		Iowa State University
Insecticide Crop Safety	KS	Ray Cloyd
		Kansas State University
Scale Efficacy	IN	Cliff Sadof
		Purdue University
Insecticide Crop Safety	MI	Terry Davis,
		Michigan State University
Thrips Efficacy	MI	Terry Davis,
		Michigan State University
Botrytis Efficacy	MI	Mary Hausbeck,
		Michigan State University
Fungicide Crop Safety	MI	Mary Hausbeck,
		Michigan State University
Fungicide Crop Safety	MI	Willie Kirk,
		Michigan State University
Leaf Spot & Anthracnose	MI	Willie Kirk,
Efficacy		Michigan State University
Leaf Spot & Anthracnose	OH	Francesca Hand,
Efficacy		Ohio State University
In Season Crop Safety	OH	Hannah Mathers, Mathers
		Environmental Science
		Service
Ornamental Grass Crop Safety	OH	Hannah Mathers, Mathers
		Environmental Science
		Service
Scale Efficacy	OH	Anand Persad,
		Davey Tree Experts Co. Ltd
In Season Crop Safety	OH	John Siefer,
		Davey Tree Experts Co. Ltd

Table 1. Ornamental Research Projects in the NC Region in 2015

Biopesticides: In 2015, the NCR conducted the following biopesticide projects (Table 2). These projects seek to advance the registration and demonstrate the efficacy of naturally occurring pest management agents. These materials often have particular importance for organic growers.

Title	Principal Investigator
Efficacy and Pbytotoxicity of Bio pesticides for management of Spotted Wing Drosophila (SWD) in blueberry	Rufus Issacs, Michigan State University
Efficacy and Pbytotoxicity of Bio pesticides for management of Spotted Wing Drosophila (SWD) in caneberries	Matt Grieshop, Michigan State University
Efficacy and Phytotoxicity of Bio pesticides on Apple for the Control of Fire Blight	George Sundin, Michigan State University
Efficacy and Phytotoxicity of Hypovirulent CHV3-GH2 on Chestnut for the control of Chestnut blight.	Dennis Fulbright, Michigan State University
Efficacy and Phytotoxicity of Biopesticiedes on tomato for control of Clavibacter	Sally Miller, Ohio State University
Efficacy and Phytotoxicity of Biopesticiedes on tomato for control of Clavibacter	Mary Hausbeck, Michigan State University

Table 2. Biopesticide Research Projects in the NC Region in 2015

Canadian Biopesticides and Minor Use Pesticides Priority Setting Workshops: Satoru Miyazaki participated in the 2015 Canadian Biopesticides and Minor Use Pesticides Priority Setting Workshops, which took place from March 24th to the 26th at the Hilton Lac-Leamy Hotel, 3 Boulevard du Casino, Gatineau, Quebec. The other participants from IR-4 included Kathryn Homa, Dan Kunkel, Edith Lurvey, Cristi Palmer, Marylee Ross and Van Starner. More than 200 people attended. Much of the NC Region is contiguous with Canada and we have many pest management problems in common. These workshops facilitated the prioritization of biopesticides and minor use pesticides projects for the 2015 field season. The Canadian minor use priority rankings are set in each separate pest category (weeds, insects and diseases) for biopesticides, food, ornamentals uses, forestry and organic crops together. The pest priority is ranked nationally with the final decision being made by consensus. Usually two pest control solution for research is chosen from the list of potential solutions (conventional pesticides and other alternatives). IR-4 was also asked for input to assist in reaching a final determination, as needed. They prefer registration candidate products to be developed jointly with IR-4.

Interactions with Wisconsin Ginseng Growers: The NCR is home to a unique specialty crop, ginseng. Marathon County, Wisconsin, produces 90% of the cultivated American ginseng grown in the United States. To date through IR-4 13 fungicides are labeled for ginseng since the research started in 2002. On-going ginseng research includes eight fungicides and one molluscicide (metaldehyde), one biopesticide demonstration project and one insecticide (cyantraniliprole) efficacy/crop safety trial.

On March 14, 2015, along with MSU's Mary Hausbeck, Department of Plant, Soil and Microbial Sciences and Satoru Miyazaki attended the 2015 Spring Wisconsin Ginseng Growers' meeting to present ginseng research results as well as provide information on the petition status of fungicides for ginseng. The ginseng growers are awaiting new labels for ginseng disease control and are very active in getting the word out to the Wisconsin federal and state legislators.

The 2015 Ginseng Research Field Day was held on August 7 in Marathon County, Wisconsin. In spite of steady rain fall over 90 growers, industry representatives, policy makers, and researchers were in attendance. Nancy Hirschhorn, USDA-FAS and Camille Q. Solberg from the Senator Ron Johnson, WI office were present. Mary Hausbeck and her staff highlighted the ongoing research trials in the various ginseng gardens of the cooperating growers. Satoru Miyazaki presented a progress report of the IR-4 ginseng research on new product registrations and the current E/CS trials for cutworm control on ginseng. Mary Hausbeck showed the evaluation results of various new and experimental products for control of ginseng diseases. They could see and hold the infected samples and learned the most important aspect of having a healthy ginseng crop for their gardens.

Great Lakes Fruit, Vegetable and Farm Market Expo, Grand Rapids, MI, December 8-10, 2015:

The NCR IR-4 program joined the MSU AgBioResearch and Extension as exhibitor at the Great Lakes Expo to promote and publicize the IR-4 Project to fruit and vegetable growers, farm marketers and greenhouse operators. With the cooperation of IR-4HQ, a poster was set up depicting how the IR-4 project helps specialty crop growers with emphasis on Michigan and other NCR crops. The IR-4 brochure, "How IR-4 Helps Michigan Growers" was well received.

IR-4 Laboratory

Laboratory Performance: The Michigan State University lab was assigned analytical responsibility for 118 residue trials from US and Canadian sites in the 2015 National Planning Meeting. As shown in Fig. 1, the laboratory productivity in terms of trials completed and reported to the IR-4 Headquarters has maintained its recent improvement with 115 trials reported in 15 analytical summary reports, with 13 additional trials completed and in draft report. Our new LC-MS/MS from Thermo Scientific has started to come into its own demonstrating excellent sensitivity as compared to the old instrument. In some instances, we have observed almost 10X the response from the same compounds if old and new instrumentation are compared. With more of Dr. Jiang's time being spent in capacity building, (see below) we have hired a new analyst to help us maintain our productivity by the name of Robin Chinnery. She is currently in training and will be working with Dr. Jiang to learn to run the Agilent LC-MS/MS for residue studies.

International Activities: International activities have been primarily in the form of capacity building and invited lectures, Dr. Jiang has traveled to Egypt and Morocco to work with international laboratories and the IR4 headquarters building international laboratory capacity for residue analysis. He also continues to work with China in development of a GLP analytical program there.

Quality Assurance Program

The Quality Assurance Unit (QAU) in 2015 monitored 74 field trials and 104 laboratory analytical trials that were conducted in the region including the USDA ARS facility at Wooster, OH. QAU conducted periodic in-life inspections of the GLP studies to assure the management that the study protocol and appropriate Standard Operation Procedures (SOPs) were followed in compliance with the EPA GLP standards (40 CFR 160), and audited the field data books, analytical raw data, analytical summary

report, and draft final report of each study to assure the data quality and integrity for GLP compliance. As part of the GLP requirements, QAU also conducted facility inspections to assure that the personnel, equipment, and test facilities were properly set up and adequate for conducting the requested GLP studies.

The personnel in the QAU that were involved in NCR studies in 2015 are:

Quality Assurance Officers	Area of Responsibility
Dr. Zhongxiao Michael Chen	Regional QAU management, inspections, and audits
Ms. Lisa Latham	Inspections and audits
Dr. Derek Killilea	ND/SD Field Sites
Dr. Bryan Jensen	UW-Madison IR-4 Research Center
Ms. Eileen Nelson	UW-Madison IR-4 Research Center (Since December 2015)

QAU Performance in Last 4 Years: In 2015, the QAU performed a total of 147 inspections and audits (Table 1). This workload had steady increases since 2009 after the closure of the Cornell University analytical lab and now it seems to be leveled off after 2012. In 2014, the draft final report audits has been dropped considerably due to uncontrollable external reasons. For calendar year 2015, we were back to normal and completed a total of 194 inspections and audits.

Opuale infough August 2015.					
Inspections or Audits	2011	2012	2013	2014	2015
Draft Final Report Audit	8	24	14	4	14
Analytical Raw Data & Report Audit	35	38	42	23	33
Field Data Book Audit	139	91	76	76	74
Lab and Field In-life Inspection	65	47	52	40	63
Facility Inspection	6	4	8	4	10
Total QA Reports	253	204	192	147	194

Table 1. Numbers of Quality Assurance Reports Accomplished in Last 4 Years with Current Update through August 2015.

EPA Inspection: There were 5 EPA inspections in the region in 2015. On April 30, 2015, EPA informed us GLP compliance inspections were scheduled on May 11 – 14, 2015 at MSU analytical lab and Dr. Bernard Zandstra's field site at MSU. The inspections were led by Mr. Mark Lehr of EPA, and accompanied by guests of Chinese Official Delegation on Pesticide GLP Program, Ministry of Agriculture, P. R. China. We were notified that the inspection would follow the old-school scheme which meant that all data would be inspected on-site. The studies selected for audits included PR10640.11-MIR16 (cyantraniliprole/sunflower) for the MSU lab and PR10667.11-MI21 (metaldehyde/bean), PR 06948.08-MI06 (clethodim/plum), and PR 06877.09- MI20, MI21, MI22, MI23, MI24, MI 25 (clethodim/cherry) for the MSU field site. During the inspection, Mr. Mark Lehr selected on-going studies of PR 11125.13-MIR04 (DPX-QGU42/mustard greens) from the MSU lab and PR 11324.15-MI248 (pyroxasulfone/celery) from the MSU field site for additional audits. There were no findings at the end of inspections.

On May 27, 2015, we received notification of upcoming EPA inspections at Dr. Brian Jenks' field site at NDSU, Minot, ND, and Mr. Mark Ciernia's field site at NDSU, Fargo, ND, scheduled for the week of June 29, 2015. The inspections would be led by Mr. Mark Lehr and followed the new-school scheme which meant that all raw data would be sent to/reviewed at EPA office. Originally EPA selected the

studies of PR10640.11-ND04 (cyantraniliprole/ sunflower) for Mr. Ciernia's field site and PR10640.11-ND02 (cyantraniliprole/sunflower), PR A5150.09-ND15, PR A5150.09-ND16 (esfenvalerate/canola) for Dr. Jenks' field site. Later, Dr. Michael Chen found out that the study of PR A5150 (esfenvalerate/canola) was withdrawn from the EPA petition and IR4 Headquarters confirmed the withdrawing letter was sent to EPA in January 2015. Consequently, the inspection on the study of PR A5150 (esfenvalerate/canola) was suspended and no replacement was made per Mr. Lehr instructions. On June 29, 2015, Mr. Lehr visited Mr. Ciernia's field site and selected an on-going study of PR 11508.15-ND280 (linuron/bean) for additional audit. On July 2, 2015, Mr. Lehr visited Dr. Jenks' field site and selected two on-going studies of PR 11344.15-ND284 (novaluron/sunflower) and PR 11383.14-ND297 (flonicamid/sunflower) for audits. Both sites finished the inspections without findings.

During Mr. Lehr's visit at MSU lab on May 11 – 13, Dr. Michael Chen discussed a previous EPA inspection at Dr. Hoy's field site in Wooster, OH. On October 28, 2013, EPA informed us that a GLP compliance inspection was scheduled on December 3, 2013, at Dr. Casey Hoy's site at the Ohio State University, Wooster, OH. The targeted trials were PR# 09655.06-OH17 (Metaldehyde/Corn) and PR# 09669.06-OH16 (Indoxacarb/Bean). However, Dr. Hoy was not conducting IR4 GLP trials since 2006 and the GLP decommission letter was sent to EPA on September 21, 2007. Based on Mr. Lehr's recall, he finished the data audits without findings and submitted his report to his supervisor. The inspection was closed without findings and without site visit.

The last EPA inspection of the year occurred on September 16, 2015 at Trevor Nichols Research Center, MSU, Fennville, MI. The inspection was led by Mr. Daniel Myers. The targeted trials are PR 10369.11-MI31 (metrafenone/peach) and PR08661.09-MI17 (diflubenzuron/peach & plum) and the selected ongoing trials were PR 01953.15-MI266 and PR 01953.15-MI279 (permethrin/ grape). The inspection was completed without findings and the official closing letter was issued on January 4, 2016.

Up to date, our region has received 31 EPA inspections in total. There are no compliance issues reported by EPA inspectors since 2000.

State	Food Use			Ornamental Use		
	Field	Efficacy	Lab	Fungicide	Herbicide	Insecticide
IL						
IN						5/ <mark>0</mark>
IA					7/0	
KS						2/0
MI	27/ <mark>55</mark>	6/ <mark>4</mark>	118/115	26/22		15/ <mark>14</mark>
MN						
MO						
NE						
ND	7/ <mark>9</mark>					
ОН		4/4		7/5	24/ <mark>0</mark>	5/ <mark>20</mark>
SD	5/ <mark>4</mark>					
WI	19/ <mark>31</mark>	2/3				
TOTAL	58/ <mark>99</mark>	12/11	118/115	33/27	31/0	27/34

 Table 4. Distribution and Status of Funded 2015 Projects (Initiated/Completed*)

*For 1/1/15 - 12/31/15. In some cases, the year of project initiation was not 2015.

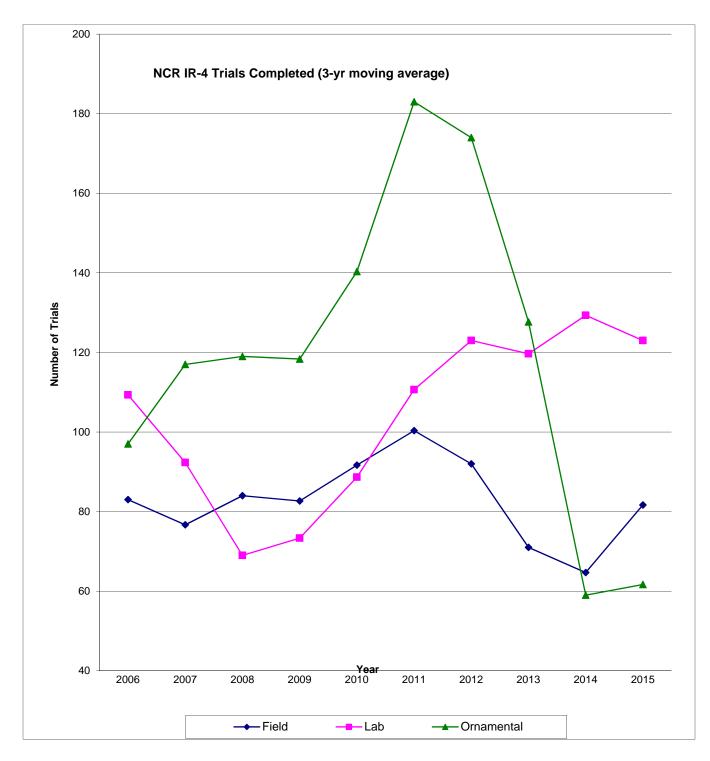


Figure 1. Record of Project Completions in the NC Region*

*as of December 31, 2015

NCR State Researchers Participating in the IR-4 Program for 2015

(* indicates State Liaison Representative)

ILLINOIS	MICHIGAN	MINNESOTA	OHIO	WISCONSIN
D. Williams*	S. Miyazaki*	V. Krischik *	D. Doohan*	D. Heider*
	T. Davis		H. Mathers	S. Chapman
	M. Hausbeck	NEBRASKA	A. Persad	R. Groves*
INDIANA	J. Wise	S. Kamble*	J. Siefer	
D.Egel*	A. VanWoerkon	m	S. Miller	
C. Sadof	B. Zandstra		F. Hand	SOUTH DAKOT
	W. Kirk	NORTH DAK	OTA	S. Clay*
IOWA	G.Sundin	R. Zollinger*		
R. Hartzler*	R. Issacs	M. Ciernia		
D. Cochran	M. Grieshop	B. Jenks		

KANSAS R. Cloyd *

Open*

MISOURI

NC Liaison Committee Officers

NC Region Administrative Advisor

D. Williams - Chairperson J. Wise - Vice Chairperson D. Heider - Secretary

D. Buhler - Administrative Advisor

MSU Leader Lab

J. Wise - NC Region Director

- Regional Field Coordinator S. Miyazaki
- S. Erhardt - Regional Lab Coordinator
- W. Jiang - Associate Regional Lab Coordinator
- L. Geissel - Research Assistant
- S. Kumar - Research Assistant
- E. Gomaa - Research Assistant
- R. Fader - Laboratory Technologist
- R. Othoudt - Part time Analyst
- QAU Coordinator Z. Chen
- L. Latham - QAU associate

Field Research Center Directors

MI: B. Zandstra (23 veg. and tree fruit crop use trials) MI: A. VanWoerkom (5 tree fruit use trials) WI: S. Chapman and D. Heider (21 veg. crop use trials).

Field QA

Z. Chen, MI/L.Latham D. Killilea, ND B. Jensen, WI E. Nelson, WI

TA